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AN INVESTIGATION OF A STERILE ACCESS TECHNIQUE FOR THE REPAIR AND ADJUSTMENT OF STERILE SPACECRAFT

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16. Abstract

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SUMMARY

This report presents the description of a unique system for the sterilization and sterile repair of spacecraft and the results of a test program designed to assess the biological integrity and engineering reliability of the system. This trailer-mounted system, designated the Model Assembly Sterilizer for Testing (MAST), is capable of the dry-heat sterilization of spacecraft and/or components less than 2.3 meters in diameter at temperatures up to 433 K and the steam sterilization of components less than 0.724 meter in diameter. Sterile access to spacecraft is provided by two tunnel suits, called the Bioisolator Suit Systems (BISS), which are contiguous with the walls of the sterilization chambers and which allow technicians to effectively be in the chambers while they are biologically isolated from the spacecraft and its environment. Asepsis is maintained by a combination of a positive differential pressure in the sterile chambers and the physical integrity of the chamber walls and the BISS. The system is monitored by integrated leak-detection systems by use of helium in the chamber gas as a tracer.

The test program was designed primarily to verify the biological and engineering reliability of the MAST system by processing simulated space hardware. Each test cycle simulated the initial sterilization of a spacecraft, sterile repair of a failed component, removal of the spacecraft from the MAST for mounting on a launch vehicle, and a sterile recycle and repair. The operations were followed by a sterility bioassay to determine whether the simulated spacecraft had become recontaminated during the sterile operations period.

The test program results indicate that the biological and engineering objectives have been attained and that this type of sterile access system is capable of achieving a high level of biological and engineering reliability. However, additional test cycles would be required to obtain sufficient statistical data to satisfy NASA planetary quarantine requirements.

INTRODUCTION

This investigation was undertaken as part of a continuing research and development program to provide techniques, procedures, equipment, and facilities to fulfill the requirements of interplanetary missions. Severe problems in this area are involved with the sterilization of planetary landers, one of which is the degradation of the reliability of the landers by the sterilization process. All efforts are being made to minimize this degradation. Two ways in which spacecraft are degraded are by sterilization after a repair has been made and by the overexposure of parts near the outer shell of a spacecraft during sterilization in an assembled form.

A sterile access technique has been conceived and developed for the sterilization, sterile assembly, repair, and recycle and repair of a planetary lander. This technique will allow the spacecraft to be sterilized in a disassembled form, assembled and tested under sterile conditions, and repaired without resterilization; thus, excessive thermal degradation is avoided. Also, recycle and repair, that is, repair after the outside of the vehicle has become contaminated, is made possible with a minimum effect on the reliability of the lander. The primary elements of this sterile access technique are threefold:

(1) The use of a large, leak-tight, sterilizable chamber operated under a slight positive pressure for sterilization, assembly, test, and repair operations,

(2) The use of a tunnel suit system that allows technicians to work on the sterile spacecraft and yet keeps them biologically isolated from it, and

(3) The use of an integrated leak-detection system to monitor the integrity of the chamber and tunnel suits during these operations.

In order to develop a working system which would embody this technique, a number of preliminary investigations and development programs have been necessary. Initial investigations in the program (refs. 1 and 2) utilized glove-box systems analogous to the conceptual system to study various procedural, operational, and mechanical aspects of the technique. Subsequent investigations have emphasized both the development of conceptual components into usable hardware (ref. 3) and a detailed study to determine the relationship between differential pressure, leak rate, and contamination probability. (See refs. 4 to 7.) The latter data were needed to provide system design guidelines.

The present investigation was initiated to provide biological, physical, and engineering data on a man-sized model which would incorporate all the full-scale components developed during the preceding investigations.

One of the primary objectives of the MAST program was to determine the efficiency of the MAST as a system designed to prevent recontamination of a sterile spacecraft during assembly and/or repair operations. Preliminary analysis indicated that in order for

this technique to meet mission requirements, a recontamination probability of one in 10 million (1×10^{-7}) would have to be proven. Attainment of this number was therefore established as one of the goals of the program. Based on work with earlier glove box systems, the MAST was expected to have a recontamination probability on the order of one in 20 million (5×10^{-8}). Another important objective of the MAST program was to determine the correlation between probabilities of recontamination which are based primarily on post-terminal sterilization bioassay data from spacecraft and those which are primarily based on leak detection and differential pressure data and do not require any post-terminal sterilization bioassay data. This objective was particularly critical to the concept because under actual mission conditions involving flight hardware and a full-scale sterile access system, post-terminal sterilization bioassay would not be allowed. (See ref. 8.)

Other objectives of the MAST program were engineering oriented. Although many engineering goals were met during the construction and acceptance testing of the MAST, there remained the objective of verifying the reliability of the system. In order for the system to attain the biological goals of the program, it had to function reliably over the entire test period.

Most of these objectives have been attained during a number of operational periods in the MAST, denoted as test cycles, during which a simulated spacecraft (SSC) has undergone manipulations similar to those that would be used for flight hardware. The manipulations were followed by a sterility bioassay of the SSC in order to determine whether recontamination had occurred during the operations period. During each test cycle, the microbial challenge (the number of organisms impinging on MAST), the leak rate of the MAST biobarrier (the barrier between the sterile and the unsterile environments), and the pressure differential across the biobarrier were measured continually in order to correlate these data with the sterility bioassay data.

The appendixes provide additional test equipment details and engineering results on the test equipment operation. Appendix A, "Description of Test Facility," is a more detailed explanation of the MAST system than is contained in the main text of this paper. Appendix B, "The Bioisolator Suit System (BISS)," contains additional details of the BISS tunnel suit system. Appendix C, "Supporting Test Equipment," details the Simulated Spacecraft (SSC) and two assay systems – the Ultrasonic Bioassay Tank System (UBATS) and the Gas Bioassay System (GBS). Appendix D, "Engineering Results," discusses some of the problems encountered with the test equipment and, in some cases, solutions to the problems are suggested.

SYMBOLS

Values are given in SI Units. The measurements and calculations were made in U.S. Customary Units.

A	area of MAST/BISS biobarrier, meters^2
c	average microbial challenge rate, organisms/meter^2/hour
c_{BB}	total microbial challenge of MAST/BISS biobarrier for a test cycle, organisms (eq. (8))
D	"D" value (hours, at temperature T_s, to give one log burden reduction)
D_E	equivalent hole diameter, meters (eq. (7))
He	helium concentration, percent by volume
K	constant, characteristic of test system (eq. (6))
L	average thickness of biobarrier, meters
N	number of sterilization operations in any test cycle
N_2	nitrogen concentration, percent by volume
P_c	probability of contamination, total of all sources (eq. (1))
$P_{c,BB}$	probability of contamination due to a violation of the MAST/BISS biobarrier, calculated from biological data (eq. (4))
$P_{c,i}$	probability of contamination due to a survivor of a particular sterilization cycle (i), (eq. (3))
$P_{c,p}$	probability of contamination due to a violation of the MAST/BISS biobarrier, calculated from "physical" data (eq. (6))
$P_{c,s}$	total probability of contamination due to a survivor from any of the sterilization cycles performed during a test cycle (eq. (2))

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Δp differential pressure, N/m^2

Q maximum total leak rate, m^3/sec

Q_B maximum BISS leak rate, m^3/sec

Q_E maximum equivalent BISS leak rate, m^3/sec

Q_M maximum MAST leak rate, m^3/sec

$R = \dfrac{P_{c,BB}}{P_{c,p}}$

S average shedding rate of BISS operators, organisms/hour

T_s sterilization temperature, K

t_b total duration of BISS operations for any test cycle, hr

t_o total duration of sterile operations for any test cycle, hr

t_s duration of any sterilization operation at maximum temperature, hr

V_{BB} number of organisms passing through MAST/BISS biobarrier during any test cycle

V_s sum of all survivors of sterilization operations for any test cycle, organisms

V_t total violations during any test cycle, organisms (eq. (5))

X constant, characteristic of test system (eq. (6))

$X_{o,i}$ initial microbial burden of a sterilization chamber and its contents previous to initiation of a particular sterilization operation (i), organisms

μ leak gas viscosity at time of maximum BISS leak, $N\text{-}sec/m^2$

ρ leak gas density at time of maximum BISS leak, kg/m^3

Nomenclature:

BAT   bioassay tank

BISS   bioisolator suit systems

EPDM   ethylene-propylene polymer

ETO   ethylene oxide

GBS   gas bioassay system

GC   gas chromatograph

HIC   humidity indicator controller

MAST   model assembly sterilizer for testing

M/C   main chamber

PIC   pressure indicator controller

PQ   planetary quarantine

rf   radio frequency

SSC   simulated spacecraft

TIC   temperature indicator controller

UBAT   ultrasonic bioassay tank

UBATS   ultrasonic bioassay tank system

DESCRIPTION OF TEST SYSTEM

MAST Trailers and Chambers

The MAST was designed as a complete sterilization system in conformance with guidelines established by the NASA planetary quarantine officer. (See ref. 8.) The

equipment was not sized to handle any particular spacecraft, but rather to handle nominal-sized hardware using the full-scale Bioisolator Suit Systems (BISS). The system was trailer-mounted to provide a relocation capability from research centers to launch service areas for use in full-scale training operations. Three trailers were required to carry the system; one for the sterilization and operations chambers, one for supporting equipment, and one for control and readout equipment. When placed side by side, these trailers interconnect to form a single system. (See fig. 1.)

The basic system consists of four sterilization chambers and two BISS, which will be discussed in a later section. The sterilization chambers are (1) the main chamber for dry-heat sterilization of major spacecraft components and for sterile assembly and repair operations with BISS, (2) the antechamber for either ethylene oxide (ETO) or dry-heat sterilization of major spacecraft components, (3) an autoclave passthrough for steam sterilization of small dry-heat-labile components, and (4) an ETO/dry-heat passthrough for sterilization of small components. This last chamber will be referred to as the dry-heat passthrough throughout the remainder of this paper. Both passthroughs have dry-heat sterilization capabilities and are integral to the wall of the main chamber.
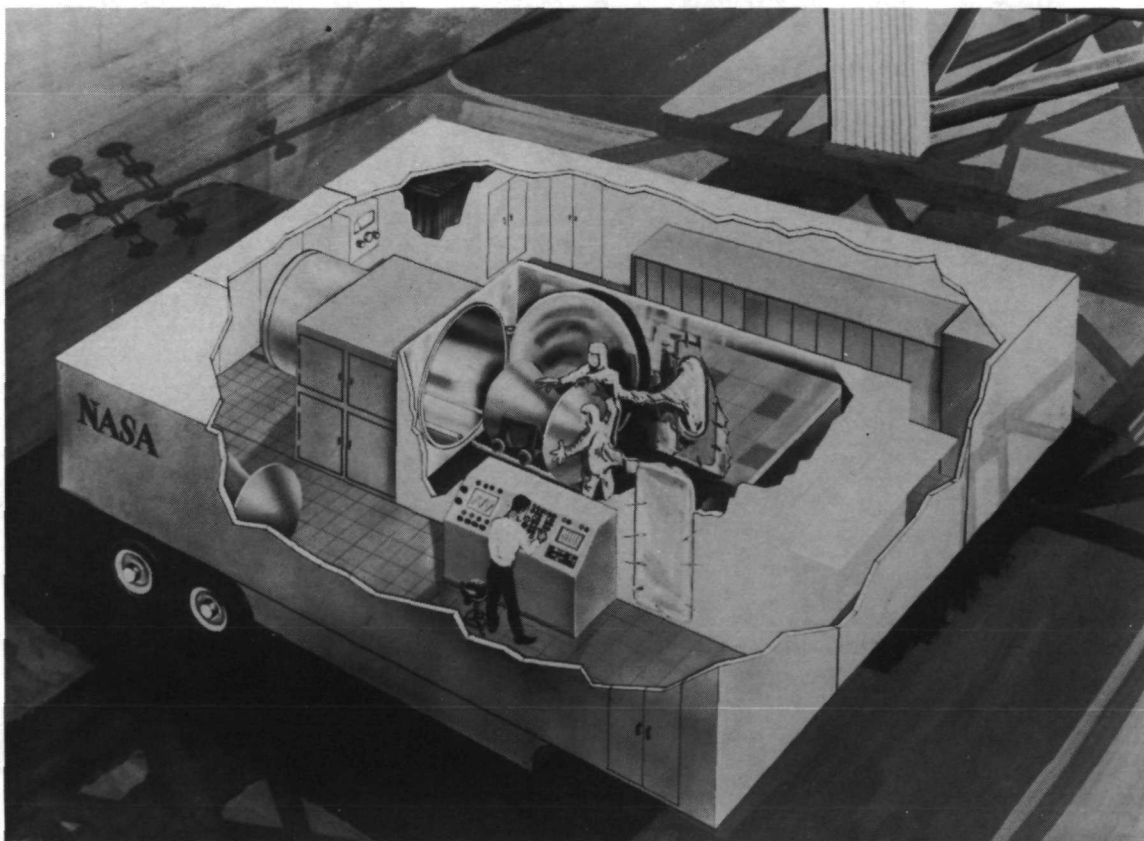

Figure 1.- Model Assembly Sterilizer for Testing (MAST). (Artist's conception, courtesy AVCO Corporation.)

The three trailers housing the system were designated: the operations trailer, the main-chamber trailer, and the equipment trailer. The general layout and equipment location in these trailers plus equipment description are discussed in subsequent sections.

Operations trailer.- The operations trailer contains the main control console, the BISS dressing room, the payload preparation area, most of the test-system monitoring instrumentation, and one BISS entry area with associated life-support and entry systems. The control of the main chamber and antechamber and meter readouts of all critical operating parameters are provided at the main control console. A bank of recorders (fig. 2) for permanent records of chamber pressures, gas incinerator temperatures, chamber wall temperatures, and chamber gas temperatures is located directly behind the main control console.

Main-chamber trailer.- This trailer houses both the main chamber and the ante-chamber, as well as much of the process instrumentation and hardware. The main chamber is fabricated of stainless-steel plate with embossed water channels welded to the exterior for heating and cooling purposes. It has an elevated perforated floor and a sus-pended filter bank which acts as the ceiling. The enclosed volumes below the floor and above the ceiling act as plenums to form a vertical laminar flow clean room. Gas (nitro-

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Figure 2.- MAST pressure and temperature recorders.

gen with a helium tracer for sterile operations) is circulated by a fan mounted in the enclosed end opposite the antechamber. Three sets of filters allow the main chamber to be operated as a Class 100 clean room.

The main-chamber interior can be heated up to 423 K for sterilization by circulating pressurized hot water through the channels. This chamber, as with all MAST chambers, is fully instrumented with iron-constantan thermocouples to monitor the temperatures of all interior surfaces during the sterilization process.

The antechamber is a cylindrical vacuum chamber which can be heated to 433 K for sterilization of the chamber interior and its contents. The antechamber is also constructed of stainless steel, but it is heated by hot water carried by stainless-steel tubing bonded to the wall and door exteriors with heat-conducting epoxy. The antechamber has an interior and exterior door to permit objects up to 2.3 meters in diameter to be passed through it into the main chamber. The doors are equipped with hand-operated pressure equalization valves which allow the BISS operators to equalize the pressure between chambers before the interior door is opened. The same procedure is utilized when opening the exterior door.

The antechamber has an elevated perforated floor which incorporates a detachable, inverted "V" track used to guide dollies transporting spacecraft components and other equipment in and out of the main chamber. A small elevator in the main chamber, also incorporating an inverted "V" track, is provided to raise or lower dollies to or from the elevated chamber floor. (See fig. 3.) The elevator is controlled from inside the main chamber by the BISS operator.

Equipment trailer.- This trailer contains most of the support equipment required to operate the main and antechambers and the two passthroughs. Included in this equipment is a hot water boiler, two chillers, vacuum systems, motor controls, and circuit breakers for pumps and motors. In addition, the autoclave and dry-heat passthroughs, their associated control and recording equipment, and one BISS entrance area with the associated life-support and entrance systems are also located in the equipment trailer.

The autoclave passthrough was designed for transferring dry heat-labile materials into the main chamber during sterile operations. It has the standard features of commercially available units including automatic cycle controls with adjustable dwell times, but it also has unique features to conform to special MAST requirements. These features include a sterile nitrogen vacuum-breaking system, dry-heat sterilization capability, gas sampling lines, and thermocouples for monitoring temperatures of the wall and contents inside the autoclave. A specially constructed rack within the autoclave allows for the sterilization and transfer of approximately 0.08 m^3 of media per test cycle.
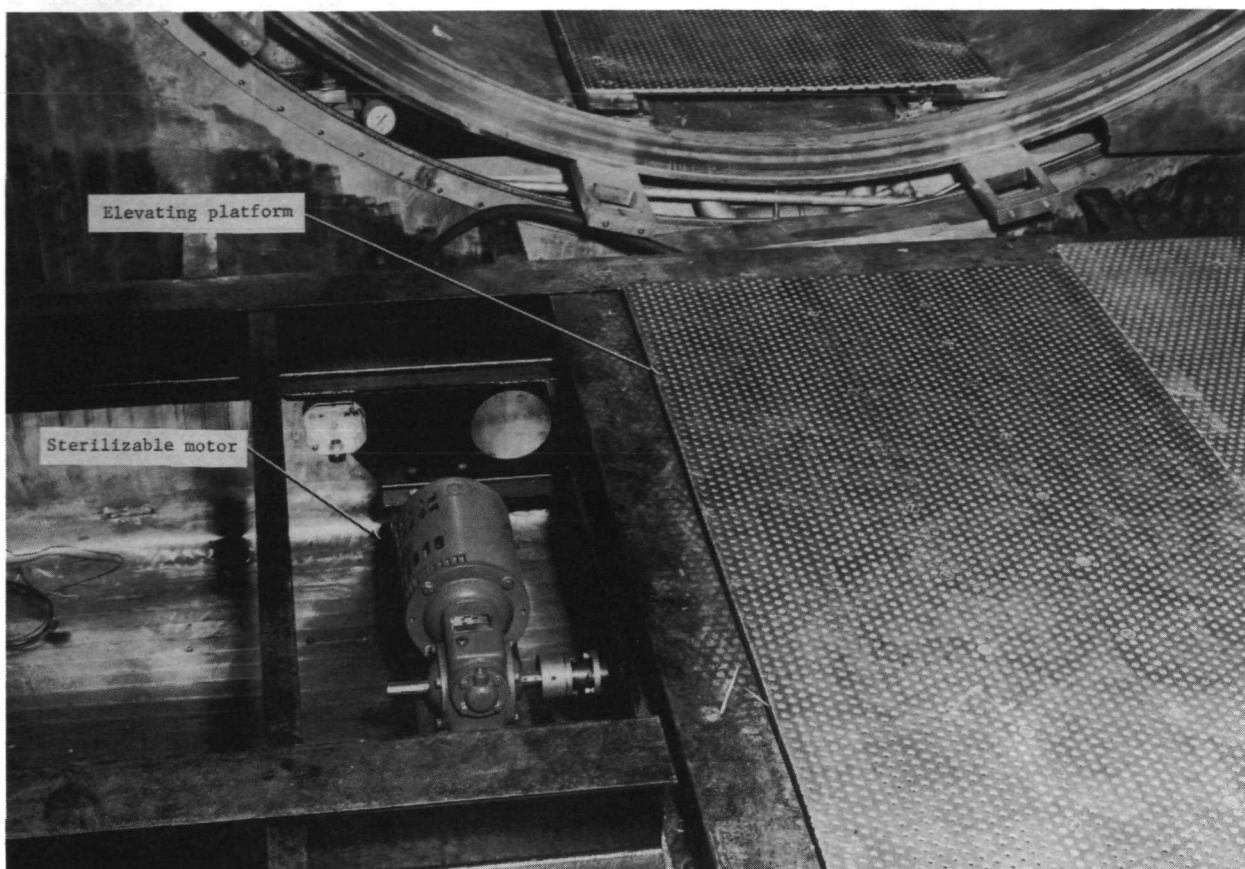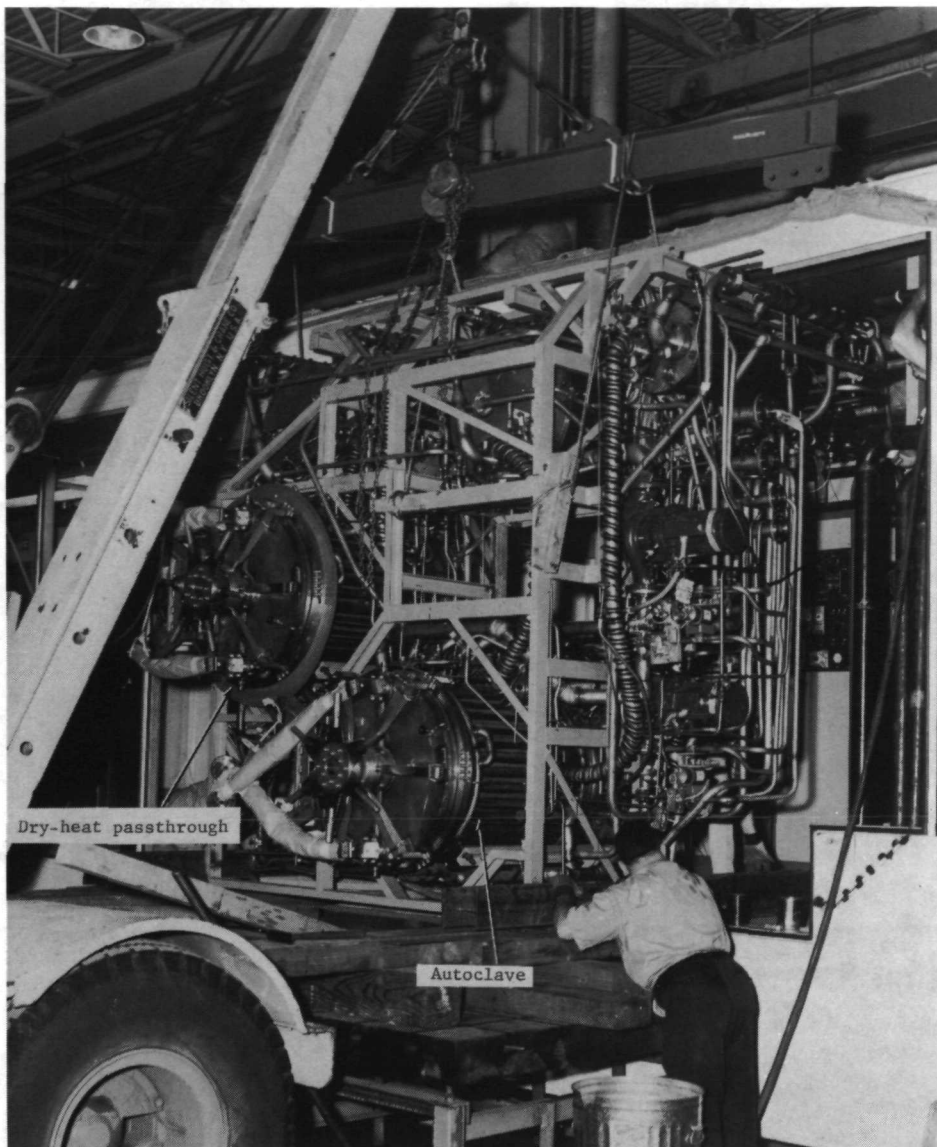
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Figure 3.- Main-chamber equipment elevator.

The dry-heat passthrough is capable of sterilization temperatures up to 433 K. It is identical to the steam autoclave except that it does not have the steam capability. It is used to transfer parts and tools into the main chambers as needed to repair, replace, or modify spacecraft components or test equipment during the sterile operations period.

The double-door construction of the autoclave and dry-heat passthrough (one door interior to the main chamber and the other exterior) allows components up to 0.724 meter in diameter to be transferred into the main chamber through either passthrough. Figure 4 shows the autoclave and the dry-heat passthrough, together with support hardware, being installed in MAST.

MAST Supporting Subsystems

Four supporting subsystems which are important to the basic concept of MAST are (1) the gas handling system, (2) the incinerator system, (3) the leak-detection system, and (4) the gas chromatograph system. These subsystems are described herein.

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Figure 4.- Installation of autoclave and dry-heat passthroughs.

Gas handling system.- This system is a dual system, one mode to provide sterile gases and the other for unsterile gases. Gases can be supplied to all chambers from a central gas distribution system, but only one gas can be supplied at a time. The gases used during these tests were air, nitrogen, and helium in the unsterile mode and nitrogen and helium in the sterile mode. Air is used in the chambers during unsterile operations. An unsterile mixture of helium and nitrogen was used to flush the air from the chambers, and a sterile mixture was used during sterilization of the chambers and sterile operations with the BISS suits. The humidity level in the chamber can be manually controlled by vaporizing demineralized water to increase it and by flushing with dry nitrogen to decrease it.

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Incinerator system.- All sterile supply gas lines, exhaust lines, and gas chromato-graph sample lines pass through electrically heated incinerators located just outside the chamber wall. These incinerators (fig. 5) were designed to heat the flowing gases to 811 K for 1 second to sterilize them.

MAST leak-detection system.- This system monitors and detects leaks in the areas of the biobarrier where leaks are most likely to occur, that is, weld seams, electrical penetrations, gas supply, and exhaust-line penetrations. It provides the information required to assess the biological integrity of the chamber walls, one of the major factors in the sterility maintenance capability of the MAST concept.

The system consists of the following major components: (1) a network of stainless-steel channels covering all penetration welds, silicone rubber covers on all pressurized water hoses within the biobarrier, and covers sealed around all electrical and gas pene-trations and viewing ports, (2) a vacuum system plumbed to the enclosure network, and (3) a helium mass spectrometer leak detector which samples the inlet to the vacuum system.

The flow rate of individual leaks can be determined by isolating the sector contain-ing the leak by closing off all other sectors with valves. An individual leak is pinpointed by backfilling the leaking sector with a helium tracer and then "scanning" the inside of the biobarrier with a portable probe attached to the mass spectrometer leak detector.
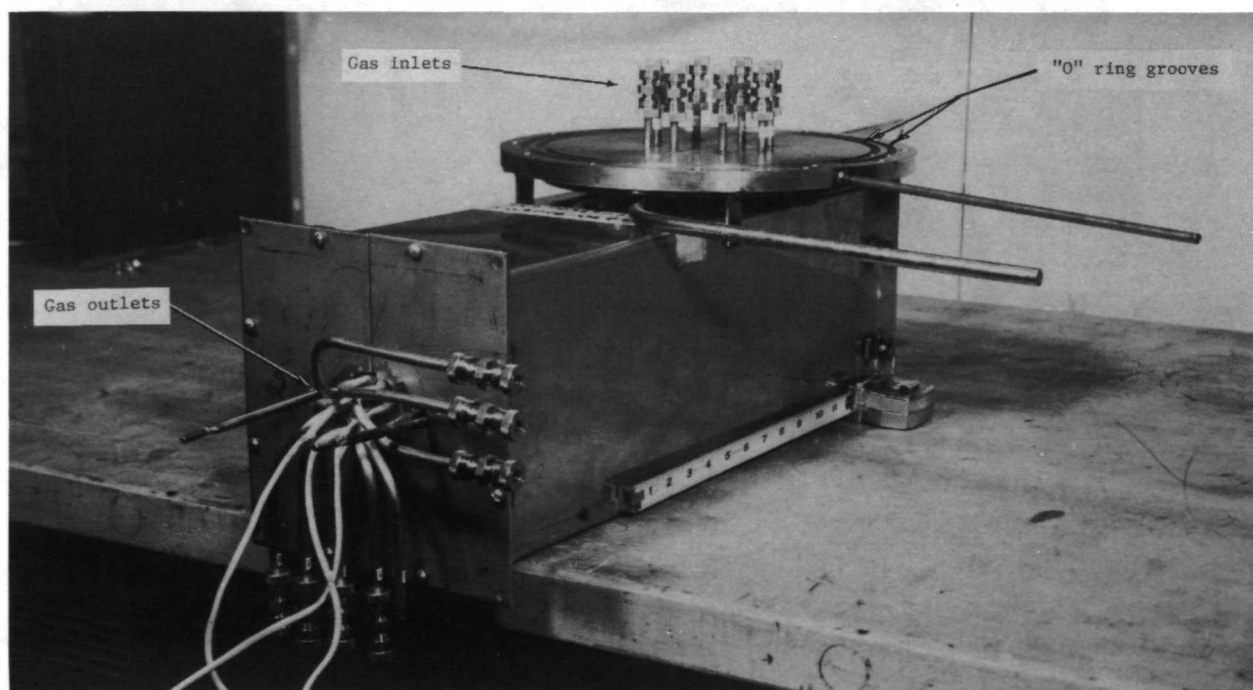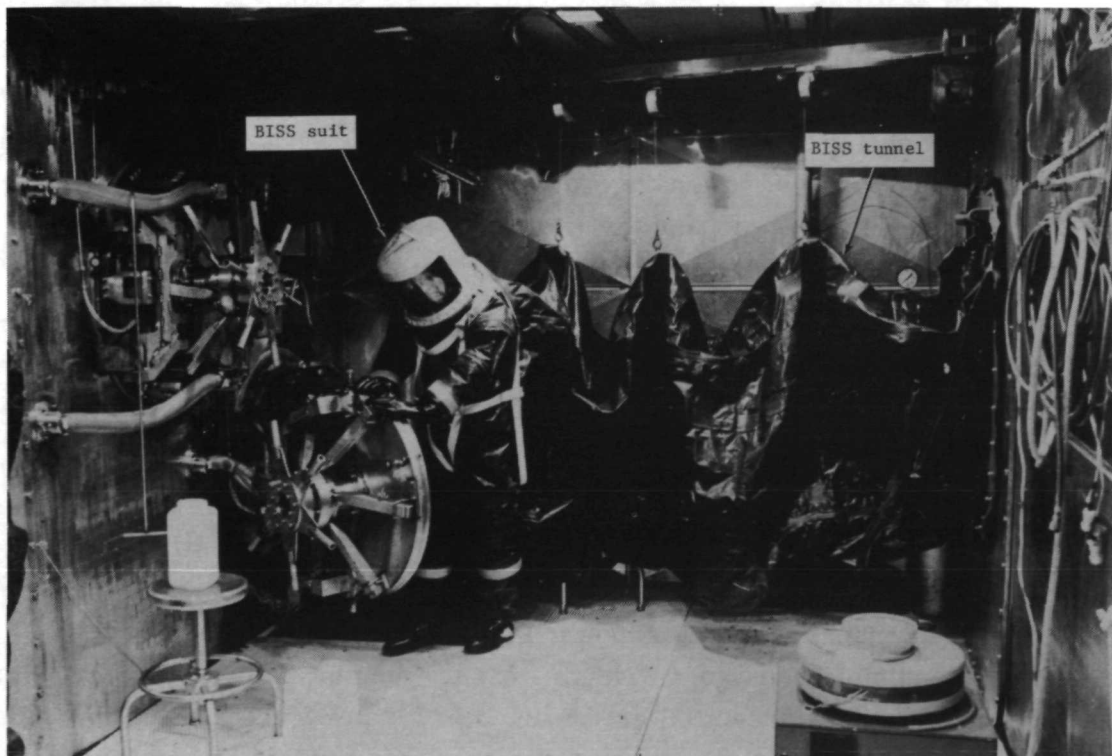

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Figure 5.- Antechamber gas incinerator.

Gas chromatograph system.- The gas chromatograph (GC) system was used to measure the concentration of the gases within the four MAST sterilization chambers. The GC separates and provides quantitative analysis of five gases; helium, oxygen, nitrogen, ethylene oxide, and dichlorodifluoromethane. Additional information describing the MAST system can be found in appendix A.

The Bioisolator Suit System (BISS)

The function of the BISS is to provide a flexible and effective biobarrier for manual assembly, repair, and adjustment of a sterile spacecraft within a sterile environment. The suit limits manual dexterity and accordingly spacecraft assembly and repair is confined to the "black box" level. The BISS consists of three major components: (1) an integral suit and tunnel made of a biologically impermeable and heat-resistant material (see appendix B for material details), (2) an air-conditioning and life-support subsystem for the suit operator, and (3) a leak-detection system.

Tunnel suit.- This component is the flexible biobarrier. It consists of a 4.75-meter-long flexible tunnel attached and sealed to the back of a flexible suit. The other end of the tunnel is mated with a biologically leak-tight attachment to the wall of the main chamber of the MAST. This arrangement makes the tunnel suit an extension of the MAST main-chamber wall. (See fig. 6.) Support mechanisms are provided to hold

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Figure 6.- Bioisolator suit system (BISS).

the suit in the proper position during operator ingress and egress. In addition, cable support mechanisms keep the tunnel off the floor to minimize abrasion and thus improve biobarrier reliability.

Air-conditioning and life-support subsystem.- This system provides cooled fresh air to the operator and removes the operator's expelled air and excess heat. It consists of an air-cooled undersuit, a compressor-condenser, an evaporator, associated blowers and piping, and control and monitoring equipment. Ambient air can be cooled and humidified or dehumidified by this system, pumped through the air-cooled undersuit, and then exhausted back into the ambient environment.

BISS leak-detection subsystem.- This subsystem provides "real-time" leak monitoring of the BISS suit and tunnel sections of the biobarrier. Unlike the MAST leak-detection system, this system operates essentially at ambient pressure and utilizes the mass flow of the BISS air-conditioning and life-support subsystem to scavenge the helium tracer gas from the spaces in the BISS suit and tunnel. A helium mass spectrometer leak detector is utilized to determine the quantity of the total BISS leak by measuring the helium concentration in a sample taken from the BISS air-conditioning exhaust line. Location and the determination of the quantity of unacceptable individual leaks is accomplished by "sniffing" the suit and tunnel inner walls with a hand-held leak-detector probe. Additional information describing the BISS system can be found in appendix B.

Supporting Test Equipment

Simulated spacecraft (SSC).- The SSC was a mock-up of a planetary lander used to simulate a spacecraft during the spacecraft assembly and repair operations. The SSC had three simulated subsystems: a landing package, an aeroshell, and a two-piece bio-canister. The aeroshell and the biocanister halves were mounted on dollies which ran on the inverted "V" track in the MAST main and antechambers.

The SSC was instrumented with thermocouples to measure temperatures of various parts during the sterilization cycles. It also contained an externally mounted pressure gage to monitor the internal pressure within the biocanister when it was sealed together.

Ultrasonic bioassay tank system (UBATS).- The UBATS, a high removal and high recovery bioassay system, was used to perform the terminal sterility assay on the simulated spacecraft (SSC) used in the MAST test program. The UBATS consists of the following major components: (1) the bioassay tank (BAT), (2) four immersible ultrasonic transducers, (3) the ultrasonic generator, power supply, and control console, (4) the recirculating pump and motor, and (5) two high-pressure membrane filter holders. (See fig. 7.) All these components except (3) are mounted on a dolly which runs on the inverted "V" track in the MAST main chamber and antechamber.
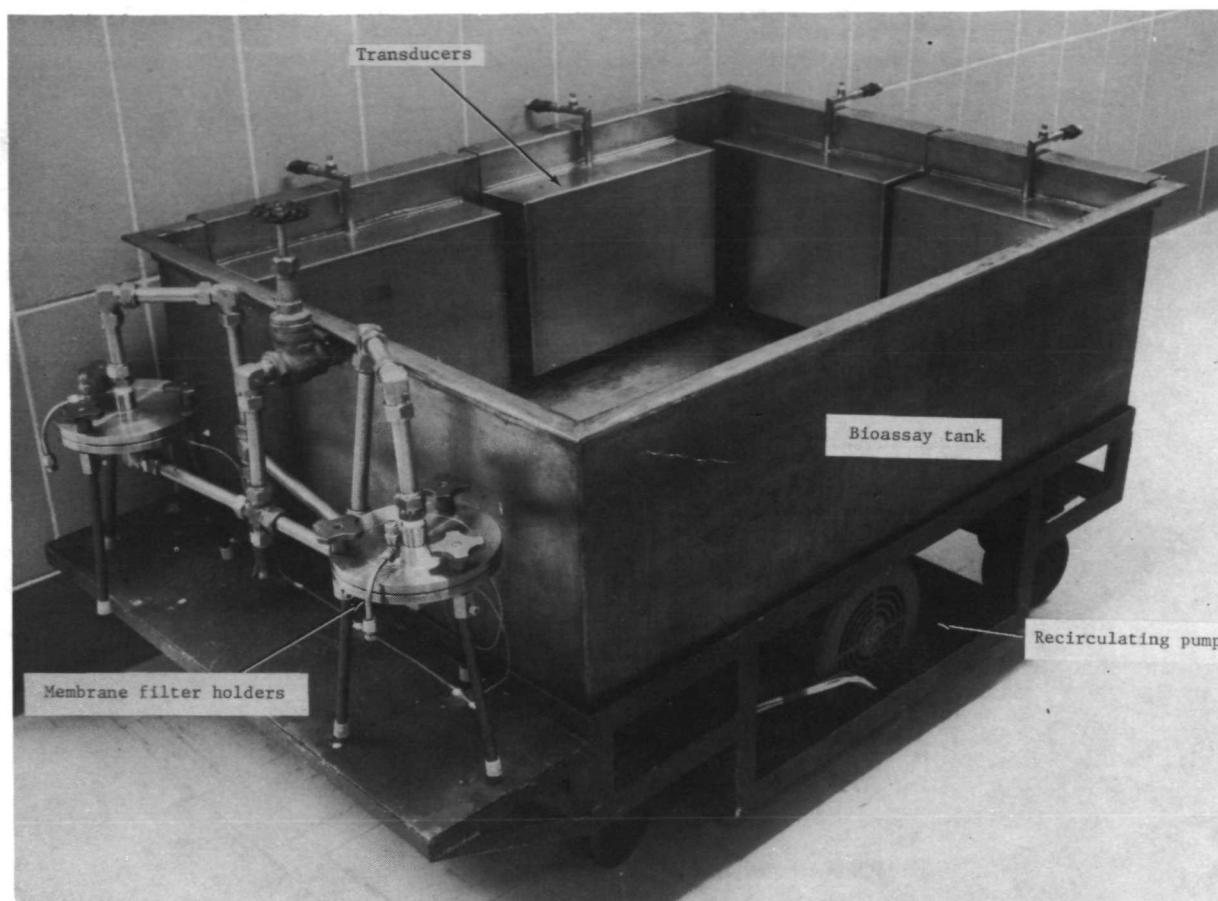
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Figure 7.- The ultrasonic bioassay tank system (UBATS).

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An object to be assayed is immersed in the fluid (a biological nutrient in water) in the BAT and treated ultrasonically to remove bacteria. The bacteria are collected on the filters by pumping the fluid through the filters, and the filters are then placed in the incubator.

Gas bioassay system (GBS).- The GBS is a modified high volume (1000 liters/min) air sampler. (See fig. 8.) This system was used to sample the nitrogen atmosphere of the main chamber during sterile operations to provide secondary assay data to aid in the analysis of the assay done after all assembly and repair operations to the SSC have been completed. Bacteria entrained in the gas sampling stream are impinged on a slowly turning disk covered with a thin layer of a dilute biological medium. A continuous flow of the medium over the surface of the disk carries the bacteria from the disk to a collection reservoir. The bacteria are then removed from the medium by filtration and the loaded filters are incubated to promote colony formation. Additional information describing the SSC, UBATS, and GBS can be found in appendix C.

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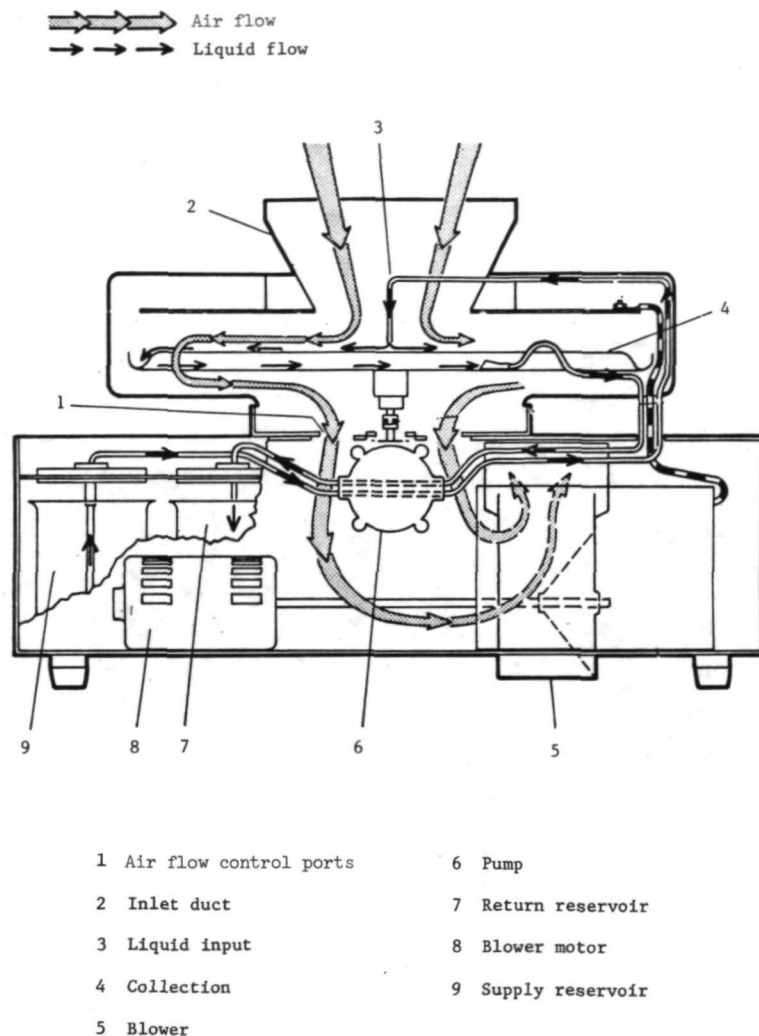|			
1	Air flow control ports	6	Pump
2	Inlet duct	7	Return reservoir
3	Liquid input	8	Blower motor
4	Collection	9	Supply reservoir
5	Blower		

Figure 8.- Schematic of the gas bioassay system (GBS).

TEST PROCEDURES AND DATA ANALYSIS

Test Program Development

A strong effort was made during the development of test procedures to simulate as closely as possible the prelaunch operations of a planetary quarantine (PQ) constrained mission requiring sterilization. Particular attention was paid to sterilization temperatures and times, spacecraft manipulations, and the types of monitoring devices. Because of time limitations, a realistic time interval for the sterile operations period could not be used, but this problem was largely overcome by augmenting the natural microbial challenge level to obtain a total challenge equivalent to that occurring naturally over the longer period. The program consisted of four test cycles being run consecutively under nearly identical conditions.

Test Cycle Procedures

A test cycle can be divided into three periods: (1) sterilization operations, (2) SSC manipulations, and (3) sterility bioassay. However, several operations which overlap these periods or occur in all periods are covered separately under a section entitled "Auxiliary operations."

Sterilization operations.- A test cycle (fig. 9) began with an initial sterilization of the three dry-heat chambers and their contents. The UBATS and GBS were sterilized in the main chamber, the disassembled SSC in the antechamber, and the repair parts, tools, etc., in the passthrough. Stainless-steel strips having an approximate population of 1×10^7 Bacillus subtilis var. niger spores were placed in eight locations throughout the three chambers to serve as sterilization controls. Thermocouple cables from the UBATS, GBS, and SSC were then connected to chamber wall feedthroughs in order to monitor the temperature of the systems during sterilization.

Just before the doors were closed for the initial sterilization, an initial burden determination was made on the SSC and the repair parts. The SSC was sampled with a vacuum probe surface sampler (ref. 9) and random samples of the repair parts were removed from the dry heat passthrough and assayed by an immersion, sonic treatment, and plating technique (ref. 10).
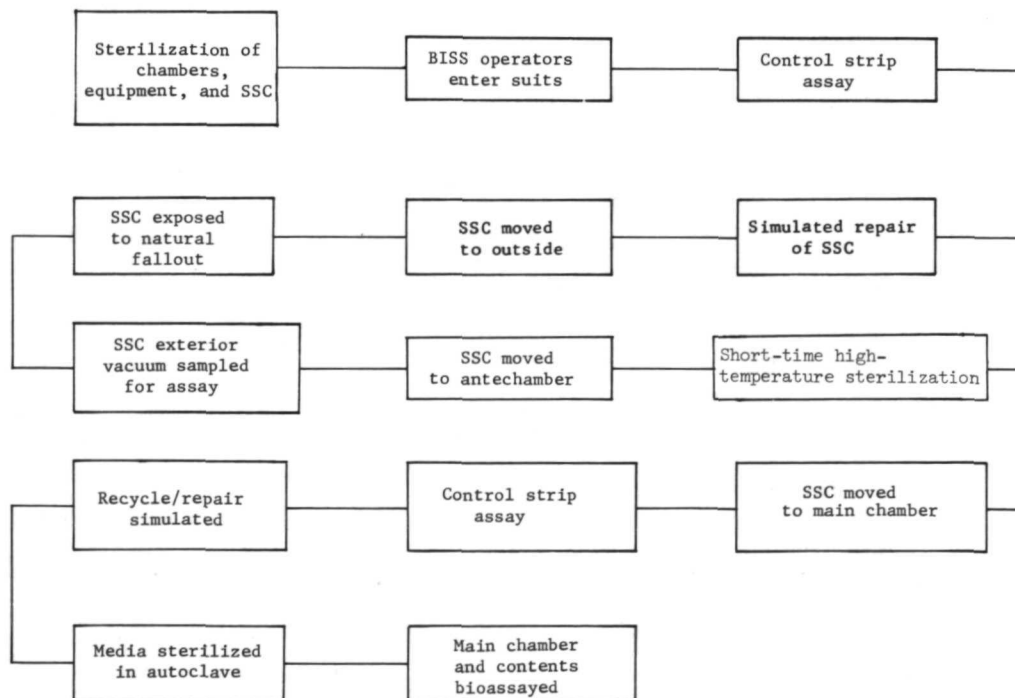

Figure 9.- Typical test cycle.

After all chamber doors were closed, the chambers were flushed with nitrogen until a concentration of 99-percent nitrogen was attained. The chambers were then heated to 398 K and maintained at that temperature for 24.5 hours. During this period, the chamber pressures were maintained at approximately 0.5 kN/m^2.

At the end of the sterilization cycle, the chamber pressures were reduced to allow operation of the BISS suits. In order to test the effectiveness of a range of pressure differentials, a different working pressure was used for each test cycle. As the chambers cooled down and the gas in them contracted, sterile nitrogen and helium were added to maintain the pressure and attain the helium level required for leak detection. The cycles utilized approximately 4-percent helium.

SSC manipulations.- After ambient temperature was reestablished in the chambers, the outer doors covering the BISS suits (BISS heating doors) were opened, and the BISS tunnel-door flanges were put in place. The BISS tunnels were then reefed back over the hard tubes. The BISS operators, after donning their air-cooled undersuits, entered the BISS suits through the hard tubes.

Initial BISS operations included placing the control strips in bottles for assay, moving the SSC from the antechamber to the main chamber, an initial repair operation, assembly and pressurization of the SSC, and the return of the SSC to the antechamber. The initial repair operation consisted of removing a small electronic module fastened to one of the SSC landing package panels by means of four small screws and a cable connector, and replacing it with an identical module sterilized in the dry-heat passthrough. This operation was selected because it represented the most delicate work that was believed possible with the relatively thick (1.15 mm) gloves of the BISS suits.

After the SSC was assembled and sealed, it was pressurized to 2.5 kN/m^2 with sterile air and passed out of the MAST through the antechamber. Then, to simulate the contamination of the biocanister which would occur while the lander was being mated to the spacecraft and the launch vehicle, the SSC was left exposed for 16 hours to the natural microbial fallout of the shop area which surrounded MAST. At the end of this period, sections of the outside of the SSC were sampled with vacuum-probe surface samplers to determine the extent of the recontamination.

In order to demonstrate the capability for sterile repair, a recycle and repair operation was included in the test program. This operation primarily consisted of a short-time, high-temperature heat cycle to sterilize the outside of the SSC without subjecting the internal components to a second heat cycle. The recycle sterilization began with the moving of the SSC into the antechamber. Two control strips containing approximately 5×10^7 Bacillus subtilis var. niger spores were placed on the SSC, the outside door was closed, and the antechamber was flushed with nitrogen until a concentration of 99 percent was attained. The antechamber was then heated up to 433 K and maintained

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at that temperature for 3 hours. During this period, a gage pressure of approximately 0.25 kN/m^2 was maintained in the antechamber and about 0.50 kN/m^2 was maintained in the main chamber. During the cooldown process, the pressure in the antechamber was maintained by using the same procedure that was used after the initial sterilization. After the cooldown of the antechamber, the pressure in all chambers was reduced to the original working pressure.

The second BISS operations period began with the opening of the inner antechamber door by the BISS operators, the placing of the control strips in bottles for assay, and the moving of the SSC into the main chamber. The SSC was then disassembled and the recycle and repair operation was performed on the landing package. This repair operation consisted of removing a small plug-in module from one of the SSC landing package panels and replacing it with an identical module that had been sterilized in the passthrough.

Sterility bioassay.- After all SSC manipulations were completed, a sterility bioassay was performed on the SSC to determine whether it had become recontaminated during the BISS operations periods. This assay was accomplished through the use of a combination of two techniques: swab-rinse-filtration for the aeroshell, and sonic removal and filtration for the landing package. Both techniques were largely based upon those described in reference 10, but a few changes had to be made because of the unique nature of the test system and the sterile environment. The data from those assays, augmented by the data from the GBS, were used to determine the total number of contaminants.

All the bioassay equipment, with the exception of the GBS, utilized the same biological growth medium, one-third strength trypticase soy broth. The GBS used this medium plus 0.1-percent polyoxyethylene sorbitan monooleate, a wetting agent. The broth was prepared in 80-liter batches, a maximum autoclave load, heated to near boiling and immediately transferred to the autoclave. The media, in 2- and 4-liter jars, were placed in the autoclave and thermocouples were placed in the middle of the most thermally remote containers. Two microbial control strips were then placed in the autoclave and the doors were closed. During the autoclave sterilization, a minimum temperature of 394 K was maintained for 20 minutes. After the autoclave sterilization cycle was completed, the inner door was opened and the BISS operators removed the containers, and with the exception of the GBS medium, dumped their contents into the UBAT where the broth cooled to ambient temperature.

Operation of the GBS was initiated as soon after initial sterilization as required to run the first autoclave cycle and pass in the GBS medium. The medium in the GBS reservoir was replenished as necessary from that passed in with each autoclave cycle. The GBS continued to run until the sterility bioassay was performed.

Ten 4-inch squares on the aeroshell were sampled with swabs moistened with broth from the UBAT and the swabs were then stored in test tubes until they could be treated

sonically. Broth from the UBAT was added to the tubes and they were treated sonically for 2 minutes in the UBAT. The broth from the tubes was returned to the UBAT, the tubes were refilled with fresh broth from the UBAT, and the process was repeated.

The landing package was treated sonically in the UBAT for 2 minutes in each of eight positions. This procedure was required in order to present each surface to the transducers and to obtain maximum removal efficiency. Two extra positions were required because the landing package could not be completely immersed when the top or the bottom was facing the transducers. The bottles containing the sterility control strips were also treated sonically in the UBATS.

Although the UBATS was designed for assay of the SSC landing package, it was utilized as a recovery system for all the assay techniques. The broth from each assay was processed through separate filters in the following sequence: (1) broth sterility control, (2) GBS media, (3) swab media, and (4) landing package assay. The last assay required at least two sets of filters because the high concentration of particulate matter recovered would plug the filters before all the broth could be filtered. Filtration times for these assays were 30, 15, 15, and 35 minutes, respectively, at an average flow rate of approximately 15 liters per minute.

After the filters were removed from the filter holders, they were placed in the tops of 150-mm glass petri dishes which had been half filled with trypticase soy agar. These tops were then placed over the empty bottoms and stacked in a stainless-steel incubation container. (See fig. 10.) The sterility control strip bottles were then sealed, flushed with sterile air, and pressurized to 2.5 kN/m^2. After the test cycle was completed, the incubation container was removed from the chamber and placed in a laboratory incubator at 305 K. After 120 hours, the container was opened in the microbiology laboratory and the filters and bottles were examined for the presence of bacterial growth. Any growth colonies found on the filters were counted and the numbers recorded. The control strip bottles were recorded as positive (growth) or negative (no growth).

Auxiliary operations.- A number of operations did not fit into any of these time frames as they were either continuous or occurred at intervals throughout the test cycle. These operations included the operation of the gas chromatograph system, the MAST leak-detection system, the BISS leak-detection system, and the monitoring and production of the microbial challenge.

The gas chromatograph system was activated at the very beginning of each test cycle. It was left on during the initial sterilization and used to monitor the helium concentration in the chambers during back-fill. During the sterile operations and final bioassay periods, it was used to monitor the helium concentration in the chambers. During most of this time, samples were taken alternately between the antechamber and the main

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Figure 10.- Incubation container.

chamber, as the passthroughs were usually open to the main chamber. Continuous, permanent machine records were provided by this system.

The MAST leak-detection system was activated at the end of the initial sterilization cycle dwell time and ran constantly until the end of the bioassay period. Although readings were taken only occasionally, the upper limit of the total MAST leak rate was regularly observed. Data from this system were manually recorded on data sheets.

The BISS leak-detection system was operated whenever BISS operators were in the main chamber. It monitored both BISS tunnel suits during these periods and produced a continuous, permanent machine record of the total BISS leak rate. When necessitated by a requirement to track down an increase in total BISS leak rate or other problems, the leak rate of a particular tunnel suit was measured and recorded instead of the total. Between BISS operations periods, it was placed on standby.

The microbial challenge monitoring was begun immediately after the completion of the initial sterilization dwell time and was continued until the end of final bioassay. Monitoring was accomplished by the fallout plate technique when the natural fallout challenge was used, and by the stainless-steel strip technique when the challenge was artifi-

cially augmented. These assays were performed according to standard practice and the data recorded on data sheets.

As mentioned earlier, the natural microbial challenge of the MAST was augmented by artificially generated bacterial aerosols. This was done in order to approximate the same number of microbial challenges that would have occurred under natural conditions during the much longer period of operation that would be expected under mission conditions. A specific number of microbial challenges were required in order to determine whether the MAST was capable of maintaining recontamination probabilities low enough to make it useful to future flight missions. The artificial aerosols were generated by a dry spore gun developed at the Langley Research Center by one of the authors and a colleague. The aerosol equipment consists of a standard nitrogen pressure cylinder, regulator, several feet of flexible high-pressure hose, and the spore gun. The latter is a commercial spray nozzle unit in which the filter unit has been replaced by a cylinder filled with 10 mg of freeze-dried Bacillus subtilis var. niger spores and covered with Teflon tape. When the unit is subjected to a pressure of approximately 1 MN/m^2, the Teflon tape ruptures, the organisms are carried through the spray nozzle by the gas flow and are emitted from the spray nozzle as an ultrafine dry spore aerosol. Sampling of this aerosol has indicated that over 93 percent of the aerosol is single spores. Each unit contained approximately 1×10^9 spores. The contents of two units, one in the operations trailer and one in the equipment trailer, were disseminated each day of sterile operations during the third and fourth cycles.

Data Reduction and Analysis

Theoretical analysis.- The probability (P_c) that a particular sterile operation cycle will contaminate a spacecraft is a function of both the probability $(P_{c,s})$ of a survivor of any sterilization cycle performed on the system or on materials entering the system and the probability $(P_{c,BB})$ of a contaminating organism violating the biological barrier of the system and coming to rest on the spacecraft. This relationship is represented as

$$P_c = P_{c,s} + P_{c,BB} - P_{c,s}P_{c,BB} \tag{1}$$

The calculation of $P_{c,s}$ is relatively straightforward, since it is the cumulative probability of survivors from all applicable sterilization operations during a cycle. The probability of a survivor from any one sterilization operation $(P_{c,i})$ is a function of the initial microbial burden or population $(X_{o,i})$, the duration of the sterilization cycle and the temperature (T_s) in the chamber during the sterilization cycle. The time required to reduce the microbial burden by one decade at the sterilization temperature is represented in the calculations by D. The expressions for determining $P_{c,i}$ and $P_{c,s}$ are given, respectively, where N is the number of sterilization cycles, as

$$P_{c,s} = \sum_{i=1}^{N} P_{c,i} \tag{2}$$

$$P_{c,i} = X_{0,i} \times 10^{-ts/D} \qquad \left(P_{c,i} \ll 1\right) \tag{3}$$

Equation (3), although derived for a homogeneous population, was utilized for these studies because the heterogeneous natural population was assumed to be a homogeneous population of the spores of a very heat-insensitive organism, Bacillus subtilis var. niger. This assumption turned out to be very realistic, as most of the initial burden was composed of the spores on the control strips.

Although the calculation of $P_{c,s}$ was very easily accomplished, the determination of $P_{c,BB}$ was considerably more difficult. The determination of this value was, in fact, one of the principal objectives of this program. This value is a characteristic of every sterility maintenance facility and it changes only when the physical characteristics of the facility itself change. The calculation of $P_{c,BB}$ from biological data was based on the premise that the biobarrier of the sterile access system acts as a filter (eq. (4)).

The probability $P_{c,BB}$ was calculated by dividing the number of organisms $\left(V_{BB}\right)$ passing through the barrier by the number of organisms $\left(c_{BB}\right)$ challenging the barrier (ref. 11). It is assumed for the purpose of this calculation that the probability of an organism coming to rest on the spacecraft after it penetrates the biobarrier is one

$$P_{c,BB} = \frac{V_{BB}}{c_{BB}} \tag{4}$$

The variable c_{BB} can be calculated directly from fallout plate and/or stainless-steel strip data, but V_{BB} had to be determined indirectly from other data. This determination was made possible by making the sterilization cycles particularly conservative and thus having a very small $P_{c,s}$. The total number of violations $\left(V_t\right)$ calculated from the sterility bioassay data was the sum of the number of survivors $\left(V_s\right)$ and V_{BB}. A very small $P_{c,s}$ is strongly indicative of a V_s of less than one organism. Under these conditions, V_{BB} is approximately equal to V_t and is expressed as

$$V_t \approx V_{BB} \tag{5}$$

By making two basic assumptions, $P_{c,BB}$ can also be calculated from "physical" data. The term "physical" is used in this context to mean a combination of physical data such as leak rates and differential pressures and biological data such as fallout rates. No terminal sterility bioassay data are required for this calculation. This determination of $P_{c,BB}$ would meet the conditions of reference 8. The assumptions required are (1) that all leaks in the biobarrier can be considered as one large leak, and (2) that

the cumulative hole allowing this large leak is one of a particular configuration. Although these two assumptions were originally designed to simplify the calculation of $P_{c,BB}$, they also make the resultant probabilities more conservative. (See refs. 6 and 7.)

The probability $P_{c,p}$ $\left(P_{c,BB}$ calculated from "physical" data$\right)$ is considered to be a function of sterile operations time t_O, equivalent hole diameter D_E, differential pressure Δp, and challenge rate c. This relationship is represented by

$$P_{c,p} = K D_E^2 c t_O e^{-X \Delta p} \tag{6}$$

The derivation of the equation and a description of the simple predictive model it represents can be found in appendix A of reference 4. The constants in the equation (K and X) are characteristics of the system involved and can be resolved by the simultaneous solution of two sets of data.

The equivalent hole diameter D_E can be determined from the following equation:

$$D_E = \left[\frac{4Q}{\pi \, \Delta p} \left(\frac{Q\rho}{\pi} + 32 L \mu \right) \right]^{1/4} \qquad \left(L/D_E \gg 1 \right) \tag{7}$$

which was derived from the Poiseuille laminar flow equation. In this equation Q is the maximum total leak rate, L is the thickness of the biobarrier, μ is the viscosity of the gas flowing through the hole, and ρ is the density of the gas. The MAST wall thickness is on the order of 2 mm and leak path hole sizes were expected to be much smaller. Thus equation (7) is valid for the equivalent hole diameter calculation.

Data recorded.- The following variables were recorded for each test cycle. Symbols are given in parentheses.

(1) Initial burden, minimum sustained temperature in kelvins, and duration in hours of the 11 sterilization operations $\left(X_O, \ T_S, \text{ and } t_S\right)$.

(2) Average biological challenge in organisms/meter^2/hour (c).

(3) Total sterile operations time during cycle in hours (t_O).

(4) Total number of violating organisms detected by the sterility bioassay $\left(V_t\right)$.

(5) Total number of organisms challenging the MAST/BISS biobarrier during a test cycle $\left(c_{BB}\right)$.

(6) Minimum differential pressure maintained throughout the sterile operations period in newtons/meter^2 (Δp).

(7) Maximum MAST leak rate during the sterile operations period in meters^3/second $\left(Q_M\right)$.

(8) Maximum BISS leak rate during the sterile operations period in meters^3/second (Q_B).

(9) Leak gas viscosity (μ) and leak gas density (ρ).

<u>Preliminary data reduction</u>.- The calculated initial burden for the sterilization operations was primarily the population of the control strips, because the natural burden was usually not significant. However, the initial burden of the SSC and the repair parts were always determined. In the former case, the highest of the 24-, 48-, or 72-hour colony counts from each aliquot of each vacuum probe sample from each major component of the SSC were totaled and then averaged to give a count/m^2. The component averages were then multiplied by the area of the component and the products were added to give the total burden. Each component had at least two sample areas of 0.093 m^2. The burden of the repair parts was determined by averaging counts for each type of part and then adding the averages. In both cases, the assay totals were added to the control strip counts to obtain the $X_{o,i}$ for their respective cycles.

The initial burden of the outside of the SSC before recycle sterilization was determined from the vacuum probe samples. The highest count from each aliquot of each vacuum probe sample was totaled and then averaged to give a count/m^2. The average was multiplied by the total area of the SSC biocanister to give its initial burden. The SSC burden was then added to the control strip count to obtain the $X_{o,i}$ for this cycle.

The initial burden for the gas incineration operations was determined by multiplying the maximum flow rate, the total sterile operations time t_o, and a conservative estimate of the microbial content of the gas per cubic meter. This calculation provided an extremely conservative count because all factors involved were maximum values.

The calculation of the average biological challenge rate c from either fallout plate or strip data was simple and straightforward. The highest counts of the plates or the counts from the strips from the 10 sampling stations were averaged. The averages for all sampling periods were added and the total divided by the total sterile operations time t_o to give an average fallout/plate/hour or fallout/strip/hour for the cycle. This value was then converted to fallout/m^2/hr.

The number of organisms which challenged the MAST/BISS biobarrier during a test cycle c_{BB} was calculated from the average biological challenge c, the number of organisms shed by the BISS operators, the total duration of BISS operations, and the area of the biobarrier A. For purposes of this calculation, it was assumed that one-half the biobarrier was exposed to the challenge of the microbial fallout; that is, only surfaces which faced upward were challenged. The shedding data were based on previous testing done on BISS operators at the NASA Goddard Space Flight Center. The number of organisms c_{BB} was calculated by using the following equation where S was the shedding rate and t_b was the total duration of BISS operations:

$$c_{BB} = \frac{cAt_o}{2} + St_b \tag{8}$$

The total number of violating organisms during the cycle V_t was determined from the results of the sterility bioassay. Essentially, V_t was the sum of all organisms detected by the combined GBS, UBATS, and swab techniques, but because none of these removal techniques were 100 percent efficient, a number of efficiency factors were included in the calculation. These factors were 6.25 for the GBS, 1.12 for the UBATS, and 27.3 for the swabbing. The first factor was based on in-house experimental data, the second on data from reference 12, and the last on a combination of data from reference 12 and the ratio of relative size of the sample area to the area of the interior of the aeroshell. Another set of factors was used to represent the recovery efficiency of the filtration method used for the sterility assay. These factors were obtained by multiplying the filter efficiency by the percentage of the total media filtered and then taking the reciprocal of the product. These factors were calculated to be 1.90 for the GBS and the swab samples, and 1.21 for the UBATS. Combined factors were 11.9 for the GBS, 51.9 for the swabbing, and 1.34 for the UBATS.

Since the results of the studies reported in references 4 to 7 showed that penetration of particles against a pressure differential is more a function of minimum differential pressures and maximum leak rates than of average pressures and average leak rates, the minimum recorded pressure, and the maximum leak rate were used to compute $P_{c,p}$ for each cycle. The maximum leak rate was the sum of the MAST and BISS leak rates at a particular time when their total was at a maximum for the cycle. The BISS leak rate Q_B was calculated by using equation (9) where Q_E was the equivalent leak rate read from the leak detector, He was the fractional helium concentration in the chambers, and the sample dilution constant was 1.18×10^4 (Sample dilution = Flow rate of BISS air-conditioning system/flow rate of leak)

$$Q_B = \frac{1.18 \times 10^4 Q_E}{He} \tag{9}$$

The MAST leak rate Q_M was the total leak rate of all 52 leak system branches as read directly from the leak-detector records.

Final data reduction.- Final data reduction was done with a simple computer program. First $P_{c,i}$ values for all sterilization operations were computed by using equation (3) and then $P_{c,s}$ was computed by using equation (2). If $P_{c,s}$ was less than 1×10^{-4}, V_{BB} was set identical to V_t. Then $P_{c,BB}$ was calculated by using equation (4) and D_E was calculated from Q and Δp by use of equation (7). The quantity $P_{c,p}$ was then calculated from D_E, c, t_o, and Δp by using equation (6).* The proba-

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*Constants K and X in equation (6) were determined from the data from test cycles 3 and 4 and then applied to the data from test cycles 1 and 2.

bility $P_{c,BB}$ was then divided by $P_{c,p}$ to give R, the ratio between the upper limit probabilities calculated from biological and physical data.

RESULTS

Sterilization Cycles Data

Four test cycles were run. The first two were run with only natural fallout as a challenge. The fallout was artificially augmented during the third and fourth cycles. Sterilization parameters are displayed in tables I and II. The computed D value is included with the direct data. As expected, the initial population $X_{0,i}$ for almost every sterilization cycle was the population of the control strip(s). Exceptions to this condition were found in the initial (cycle 1) and recycle (cycle 5) sterilizations. However, there were no cases where the natural population exceeded 5 percent of the control strip population.

The duration of the sterilization cycles t was in most cases that indicated in the test cycle procedures, with the exception of one dry-heat cycle (no. 2) in test cycle 3, where the sterilization cycle was shortened to 14 hours because of boiler failure. In a few cases, the sterilization time was extended slightly because the minimum temperature had been less than the set point.

TABLE I.- STERILIZATION DATA FROM TEST CYCLES 1 AND 2

Sterili-zation cycle	Test cycle 1				Test cycle 2			
	$X_{0,i}$	t	T_s	D	$X_{0,i}$	t	T_s	D
1	4.65×10^8	24.5	397	1.16	4.50×10^8	24.7	394	1.43
2	1.50×10^8	24.5	399	.950	1.50×10^8	24.7	398	1.00
3	1.50×10^8	.360	400	5.20×10^{-3}	7.50×10^7	.333	394	1.65×10^{-2}
4	1.50×10^8	.410	405	2.00×10^{-3}	7.50×10^7	.333	394	1.65×10^{-2}
5	1.50×10^8	3.20	431	7.50×10^{-2}	7.67×10^7	3.09	431	7.50×10^{-2}
6	1.50×10^8	.510	391	3.65×10^{-2}	7.50×10^7	.333	395	1.45×10^{-2}
7	1.50×10^8	.330	395	1.30×10^{-2}	7.50×10^7	.333	394	1.65×10^{-2}
8	3.60×10^5	3.40×10^{-4}	780	4.40×10^{-6}	3.60×10^5	3.40×10^{-4}	789	3.80×10^{-6}
9	3.60×10^5	3.40×10^{-4}	819	2.45×10^{-6}	3.60×10^5	3.40×10^{-4}	805	3.20×10^{-6}
10	3.60×10^5	3.40×10^{-4}	811	2.80×10^{-6}	3.60×10^5	3.40×10^{-4}	850	1.70×10^{-6}
11					7.50×10^7	.333	394	1.67×10^{-2}

TABLE II.- STERILIZATION DATA FROM TEST CYCLES 3 AND 4

Sterilization cycle	Test cycle 3				Test cycle 4			
	$X_{0,i}$	t	T_s	D	$X_{0,i}$	t	T_s	D
1	1.76×10^8	21.4	395	1.30	1.76×10^8	24.5	396	1.22
2	6.01×10^7	14.0	401	.725	5.86×10^7	24.5	399	.900
3	5.86×10^7	.350	394	1.80×10^{-2}	5.86×10^7	.333	393	2.00×10^{-2}
4	5.86×10^7	.333	392	2.30×10^{-2}	5.86×10^7	.333	394	1.80×10^{-2}
5	3.13×10^7	3.08	432	7.30×10^{-2}	5.86×10^7	3.00	431	7.50×10^{-2}
6	5.86×10^7	.375	394	1.68×10^{-2}	5.86×10^7	.333	394	1.80×10^{-2}
7	5.86×10^7	.333	393	2.00×10^{-2}	5.86×10^7	.333	394	1.65×10^{-2}
8	3.60×10^5	3.40×10^{-4}	811	2.90×10^{-6}	3.60×10^5	3.40×10^{-4}	811	2.80×10^{-6}
9	3.60×10^5	3.40×10^{-4}	733	8.50×10^{-6}	3.60×10^5	3.40×10^{-4}	811	2.80×10^{-6}
10	3.60×10^5	3.40×10^{-4}	733	8.50×10^{-6}	3.60×10^5	3.40×10^{-4}	811	2.80×10^{-6}
11	2.93×10^7	.350	394	1.80×10^{-2}	5.86×10^7	.410	394	1.65×10^{-2}

The variation of the D values was inversely proportional to the temperature variation. Dry-heat values varied from 0.725 to 1.43 hours for the low-temperature cycles and from 7.30×10^{-2} to 7.50×10^{-2} hour for the high-temperature cycles. Autoclave D values varied from 2.00×10^{-3} to 3.65×10^{-2} hour and the incinerator D values varied between 1.70×10^{-6} and 8.50×10^{-6} hour.

The probability of a contamination by a survivor of these sterilization cycles $P_{c,i}$ and the total probability of a contamination due to a survivor of any of the sterilization cycles in any one test cycle $P_{c,s}$ are shown in table III. The small probabilities of survival reflect the conservatism planned in the sterilization cycles. Only in a few cases was the probability greater than was desired (1.00×10^{-10}). The exceptions were due to temporary equipment failures or control failures which went undetected by the operators and the temperature was allowed to go below the set point for a significant period of time. The extremely small probabilities resulting from incinerator sterilization $(P_{c,8,9,10})$ were the results of initial microbial population estimates being based on air, rather than on dry nitrogen and helium, and of the conservative temperature requirement imposed on the incinerator construction. It should be noted that ultraconservatism in incinerator sterilization cycles inflicts no penalty on the sterilized item, whereas the same philosophy applied to the sterilization of spacecraft or assay media incurs penalties such as loss of reliability and loss of sensitivity. As can be seen in table III, the $P_{c,s}$ for each test cycle is essentially the sum of only one or two of the $P_{c,i}$ values of that cycle, the others being too small to have any significant impact. The significant $P_{c,i}$ values were usually from the initial dry-heat sterilization cycle or one of the autoclave cycles, or in one case, both. Most important, however, is that all the $P_{c,s}$ values were small enough to insure that V_s, the number of violations due to survivors of the sterilization cycles,

TABLE III.- OUTPUT DATA FROM TEST CYCLES

Variable	Output for test cycle —			
	1	2	3	4
$P_{c,1}$	3.22×10^{-13}	2.10×10^{-9}	5.94×10^{-9}	1.42×10^{-12}
$P_{c,2}$	2.18×10^{-18}	2.58×10^{-17}	2.80×10^{-12}	3.38×10^{-20}
$P_{c,3}$	*	4.80×10^{-13}	2.03×10^{-12}	1.24×10^{-9}
$P_{c,4}$	*	4.80×10^{-13}	1.85×10^{-7}	1.74×10^{-11}
$P_{c,5}$	3.04×10^{-35}	4.57×10^{-34}	1.90×10^{-35}	5.54×10^{-35}
$P_{c,6}$	1.57×10^{-6}	7.86×10^{-16}	2.71×10^{-15}	1.74×10^{-11}
$P_{c,7}$	5.97×10^{-18}	4.80×10^{-13}	1.24×10^{-9}	3.59×10^{-13}
$P_{c,8}$	*	*	*	*
$P_{c,9}$	*	*	*	*
$P_{c,10}$	*	*	3.50×10^{-35}	*
$P_{c,11}$	**	8.37×10^{-13}	1.02×10^{-12}	8.02×10^{-18}
$P_{c,s}$	1.57×10^{-6}	2.16×10^{-9}	1.92×10^{-7}	1.27×10^{-9}
$P_{c,BB}$	5.46×10^{-8}	5.99×10^{-8}	2.13×10^{-10}	1.50×10^{-8}
ρ	1.11	1.12	1.11	1.13
μ	1.77	1.77	1.77	1.77
Q_B	6.21×10^{-9}	1.10×10^{-8}	6.00×10^{-9}	1.64×10^{-9}
Q	6.79×10^{-9}	1.16×10^{-8}	6.58×10^{-8}	2.22×10^{-9}
D_E	1.60×10^{-3}	1.65×10^{-3}	2.55×10^{-3}	1.01×10^{-2}
$P_{c,p}$	2.86×10^{-6}	1.78×10^{-7}	***	***
R	1.91×10^{-2}	.336	***	***

*Probability less than 1.00×10^{-35}.

**No sterilization cycle 11 for test cycle 1.

***Since constants K and X were calculated from test cycles 3 and 4 data, they cannot be applied to the calculation of $P_{c,p}$ for these cycles. The ratio R cannot be calculated without $P_{c,p}$.

was always less than one. Therefore, V_t equaled V_{BB} for all test cycles. In fact, $P_{c,s}$ was actually smaller than $P_{c,BB}$ in two of the four cycles.

Sterile Operations Data

Sterility maintenance parameters are presented in table IV. Included are all variables and constants required to calculate $P_{c,BB}$ and $P_{c,p}$, many of which are the results of preliminary calculations and data reduction.

TABLE IV.- BIOBARRIER DATA FROM TEST CYCLE

Variable	Biobarrier data for test cycle –			
	1	2	3	4
c_{BB}	1.83×10^7	1.67×10^7	4.69×10^9	2.47×10^{10}
V_t	*0(1)	*0(1)	*0(1)	371
He	.054	.045	.059	.044
N_2	.946	.955	.941	.956
Q_E	2.84×10^{-14}	4.20×10^{-14}	3.00×10^{-14}	6.10×10^{-15}
Q_M	5.80×10^{-10}	5.80×10^{-10}	5.80×10^{-10}	5.80×10^{-10}
Δp	49.80	74.70	7.47	*0(0.01)
L	6.60×10^{-4}	6.60×10^{-4}	6.60×10^{-4}	6.60×10^{-4}
**K	1.22×10^{-3}	1.22×10^{-3}		
c	3.70×10^3	3.07×10^3	9.97×10^5	4.40×10^6
t_o	59.47	64.88	56.94	57.95
**X	.11	.11		

* The number in ( ) was used in place of the variable in equations which are invalid when this variable is zero.

** These constants were computed from the data from test cycles 3 and 4.

The total biological challenge to the MAST biobarrier during the sterile operations period c_{BB} is the sum of the fallout challenge and the challenge from the shedding of micro-organisms by the BISS operators (eq. (8)). During the first two test cycles, the latter source made a small but significant contribution to the total challenge, but during the second two test cycles, when artificial challenge was added to the natural fallout, the shedding was not a significant factor. The average c_{BB} for the latter cycles was roughly 800 times the average c_{BB} for cycles 1 and 2.

According to the terminal bioassay, the first three test cycles were sterile, whereas the last was contaminated. Examination showed 239 colony-forming centers, one from the swab assay and the rest from sonic treatment of the landing package. Application of the combined assay efficiency factors produced a V_t for test cycle 4 of 371. As noted in table IV, for test cycles 1 to 3, one was used instead of zero for the calculation of $P_{c,BB}$ because equation (4) is invalid when V_t equals zero. This condition resulted in the $P_{c,BB}$ values for these test cycles being upper limits.

The helium and nitrogen concentrations presented in table IV are the gas fractions at the time of the maximum equivalent BISS leak rate Q_E for that test cycle. The helium concentration was used to calculate the maximum BISS leak rate Q_B, and both were used

to calculate the leak gas density ρ and viscosity μ. Helium concentrations ranged from 4.4 to 5.9 percent among the four test cycles. The Q_E values are also shown in table IV, but the leak rates are not comparable at this point.

The maximum MAST leak rate Q_M was applied to all test cycles. This value was actually determined at the end of test cycle 4, when each major leak manifold area was tested separately and the leak rates for each were totaled. The rationale for this procedure was that since, with one exception, none of the MAST leaks were repaired during the test program, the maximum leak rate would occur at the end of the last test cycle.

The minimum differential pressure across the biobarrier Δp was one of the most difficult parameters to control and to measure accurately. Accuracy in the determination of Δp was particularly critical in light of its exponential importance in the calculation of $P_{c,p}$ and its use in the calculation of D_E which, in turn, is used to calculate $P_{c,p}$. (See eqs. (6) and (7).) One of the problems was that the differential pressure control was not sufficiently sensitive. Examples of this problem are test cycles 1 and 2, where the minimum Δp was supposed to be 124.5 N/m^2, and test cycle 3, where the minimum Δp was supposed to be zero. Part of this problem was due to human error and part was due to inadequate control and recording equipment.

As noted in table IV, 0.01 N/m^2 was substituted for zero Δp in the computation of the equivalent hole parameter D_E for test cycle 4 because equation (7) is invalid when Δp is equal to zero. This substitution resulted in an upper limit for D_E.

The constant L, the thickness of the biobarrier, that is, the length of the equivalent hole, was determined from the thickness of the BISS suit and tunnel material. This part of the biobarrier was selected because it was representative of the areas most likely to contain significant leaks.

The microbial fallout rates c were, for reasons explained in the discussion on c_{BB}, roughly proportional to the c_{BB} values for their respective test cycles. The relatively high natural fallout rates (test cycles 1 and 2) were due to high personnel concentrations and a general lack of housekeeping operations.

The total sterile operations time t_o was generally close to the 61 hours originally estimated for this period, which included all activities from the beginning of cooldown from the initial sterilization cycle to the end of the sterility bioassay procedure.

The constants K and X (see eq. (6)) were computed from the data of test cycles 3 and 4 and applied to the data of test cycles 1 and 2 to calculate $P_{c,p}$. This arrangement was selected because the calculation of K requires a Δp equal to zero. Test cycle 3 was selected for the calculation of the constant X because it had the highest c_{BB} and the lowest Δp of the remaining cycles. It is particularly important to note that the magnitude of X is linearly and inversely proportional to Δp, whereas the other

parameters have much less of an effect on the magnitude of X. Since $P_{c,p}$ is exponentially proportional to X, another route is available by which Δp strongly influences the magnitude of $P_{c,p}$. An example of this effect can be seen if Δp for test cycle 3 had been 4.98 N/m^2 rather than 7.47 N/m^2, then X would have been 1.27 rather than 0.11, and the $P_{c,p}$ for test cycle 1 would have been 1.70×10^{-29} rather than the 2.86×10^{-6} shown in table III. This difference in Δp is within the potential error of the differential pressure control system.

In general, the data obtained from the sterile operations part of the test program was adequate although the necessity of making approximations and/or conservative estimates of the data for data-reduction purposes changes the resultant values from definitive values to upper limits.

Final Data Reduction

The results of the final data reduction are presented in table III. The first variable in this category is $P_{c,BB}$, the probability of a contamination due to the violation of the MAST biobarrier calculated from biological data. As previously mentioned, the $P_{c,BB}$ values for cycles 1, 2, and 3 are upper limits, and only cycle 4 produced a definitive $P_{c,BB}$. Therefore, it could be said that the upper limit of $P_{c,BB}$ for the MAST is 5.99×10^{-8} whereas its actual value is in the region of 1.50×10^{-8}. If all test cycles were treated as one experiment, the overall $P_{c,BB}$ would be approximately 1.26×10^{-8}, which is comparable with the test cycle 4 data. However, the confidence in these values is obviously low.

The remainder of the variables in table III is concerned with the calculation of $P_{c,p}$, the probability of a contamination due to the violation of the MAST biobarrier calculated from "physical" data. The variables ρ, the leak gas density, and μ, the leak gas viscosity, varied only slightly from test cycle to test cycle. For μ in particular, these variations were not significant.

The maximum BISS leak rates Q_B provide the first opportunity to compare this type of data. Note that the Q_B values for test cycles 3 and 4 are lower than those for cycles 1 and 2. This result most likely is due to the loss of sensitivity of the BISS leak-detector system, as it was expected that the increase noted in cycle 2 would continue in cycles 3 and 4. Another possibility for the decrease in Q_B noted in test cycles 2, 3, and 4 is the sealing and repair operations on the BISS suit material after each test cycle.

CONCLUDING REMARKS

The sterile access technique, as embodied in the MAST/BISS system, is capable of maintaining a degree of aseptic conditions which should be acceptable to any planetary

quarantine-constrained mission operating under the present requirements of NASA. The recontamination probability established as a goal for the program (1×10^{-7}) was surpassed by a factor of two. Three out of four cycles of 61 hours duration were sterile, one of the sterile runs facing ultrahigh challenge rates.

The recontamination probabilities calculated by a method which utilizes primarily physical data such as leak rates and differential pressures are conservative estimates of the probabilities based primarily upon sterility bioassay data. Although this relationship is not a definite mathematical one, it does provide a means for estimating this probability and for meeting the requirements of NASA with respect to post-terminal sterilization bioassay and certification of sterility. A more exact definition of this relationship is needed.

There are no unsolvable biological problems associated with the use of a facility based on the sterile access technique for the sterilization, sterile assembly, and sterile repair of a planetary quarantine-constrained spacecraft. Although the engineering problems posed by such an undertaking will be difficult, it is believed that solutions to these problems lie within present capabilities.

Langley Research Center,
> National Aeronautics and Space Administration,
>> Hampton, Va., December 21, 1972.

APPENDIX A

DESCRIPTION OF TEST FACILITY

MAST Trailers and Chambers

Trailers.- The MAST system is composed of three trailer-mounted components which are assembled to form a complete facility. These components are the equipment trailer, the chamber trailer, and the operations trailer. The chamber trailer is the center component and contains the main and antechambers and the sensors, instrumentation, and other hardware required to support operations in these chambers. The operations trailer is the center of activity during sterilization operations. This trailer houses most of the MAST supporting subsystems, half of the BISS supporting equipment, and the control and recording equipment for the main and antechambers. The equipment trailer contains the processing equipment for temperature control of the chambers, as well as regulators, manifolds, and plumbing for the gas handling system.

Main chamber.- The main chamber is the site of "sterile" assembly and repair operations utilizing the BISS suits. This chamber is the focus of all activities. Three sets of filters permit the main chamber to operate as a Class 100 clean room during the last stages of spacecraft assembly and any repair operations. The speed of the circulating blower is continuously variable to provide specific flow rates for proper clean room operations and for uniformity of temperature during the sterilization of the chamber. The floor of the main chamber is perforated aluminum plate.

The main-chamber wall panel sections were welded and the weld surfaces inside the chamber were ground to a 1.6-micron root-mean-square finish. This finish was required to avoid harboring large numbers of micro-organisms on the rough weld surfaces, some of which might survive the sterilization operation and later migrate to a sterile spacecraft.

An extended spine heat exchanger (fig. 11) is located in the gas return duct just above the circulating blowers. Water is heated under pressure to slightly above 398 K and circulated through the heat exchanger to heat the gas returning to the chamber. The gas, in turn, heats those elements in the main chamber which are not directly heated by circulating superheated water. Principal among these items are the floor, the SSC, the BISS tunnel suits, and other associated hardware such as the UBATS and the GBS.

There are several visual monitoring ports in the chamber walls, one over the control console in the operations trailer and two in the wall adjacent to the equipment trailer.

The main chamber has five 61-pin electrical feedthrough connectors, 50 pairs of thermocouple feedthrough connectors, and three rf-shielded coaxial feedthrough connec-
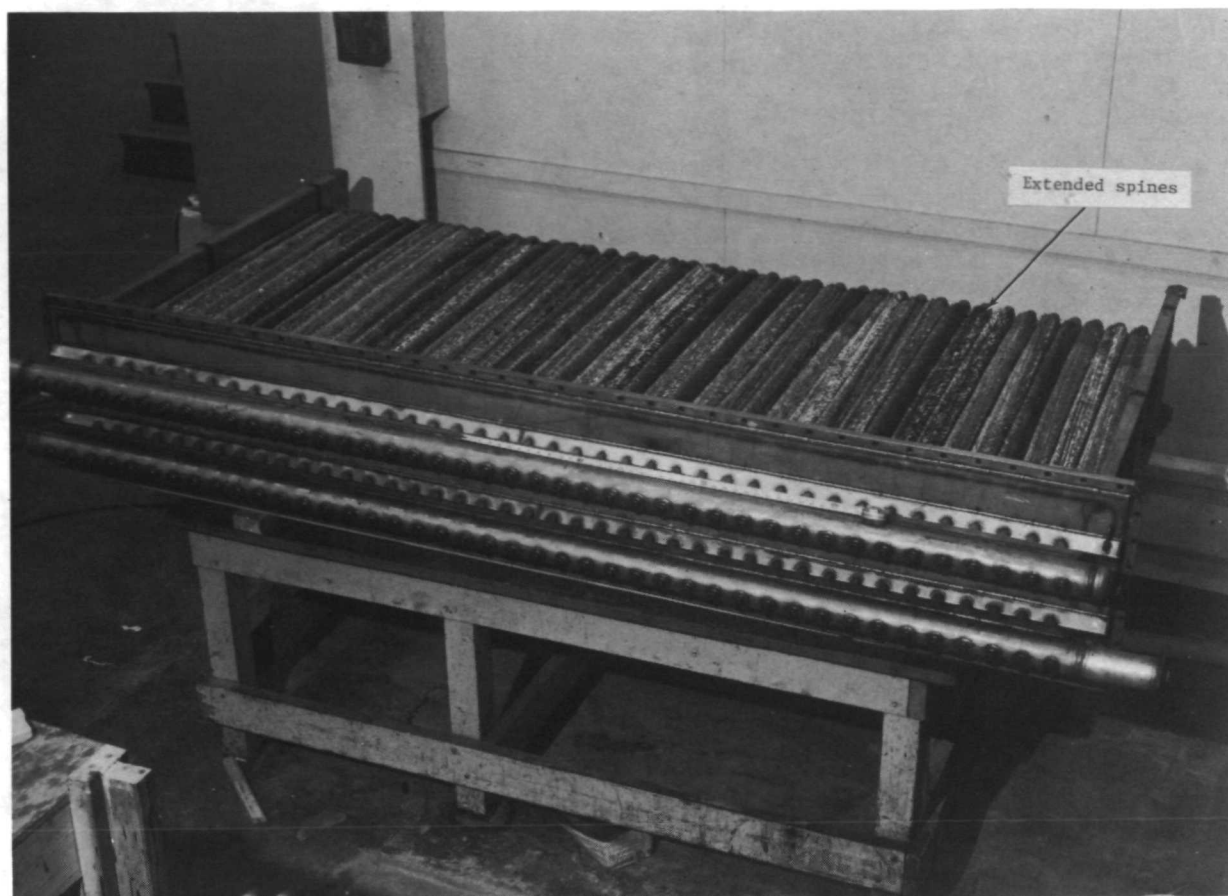
L-73-206

Figure 11.- Main-chamber heat exchanger.

tors. These connectors provide feedthroughs for power for equipment operation and for signals from monitoring instrumentation.

Antechamber.- The antechamber serves as a double-door passthrough for the transfer of the SSC into and out of the main chamber (fig. 12). This chamber, located in the chamber trailer, also provides a means of administering a short-time, high-temperature sterilization cycle to the contaminated exterior of the SSC after it has already been sterilized but is being returned for repairs. The antechamber is a cylindrical vacuum chamber attached to the main chamber at the end opposite the gas return duct. The antechamber has two 61-pin electrical feedthrough connectors and 20 pairs of thermocouple feedthrough connectors.

Four taps have been provided through the wall of the chamber for gas chromatograph sampling. They are located at the top and bottom of the chamber, at midheight of one wall, and in the gas-return duct. In addition, six tubing feedthroughs have been installed and blanked off for future contingencies.
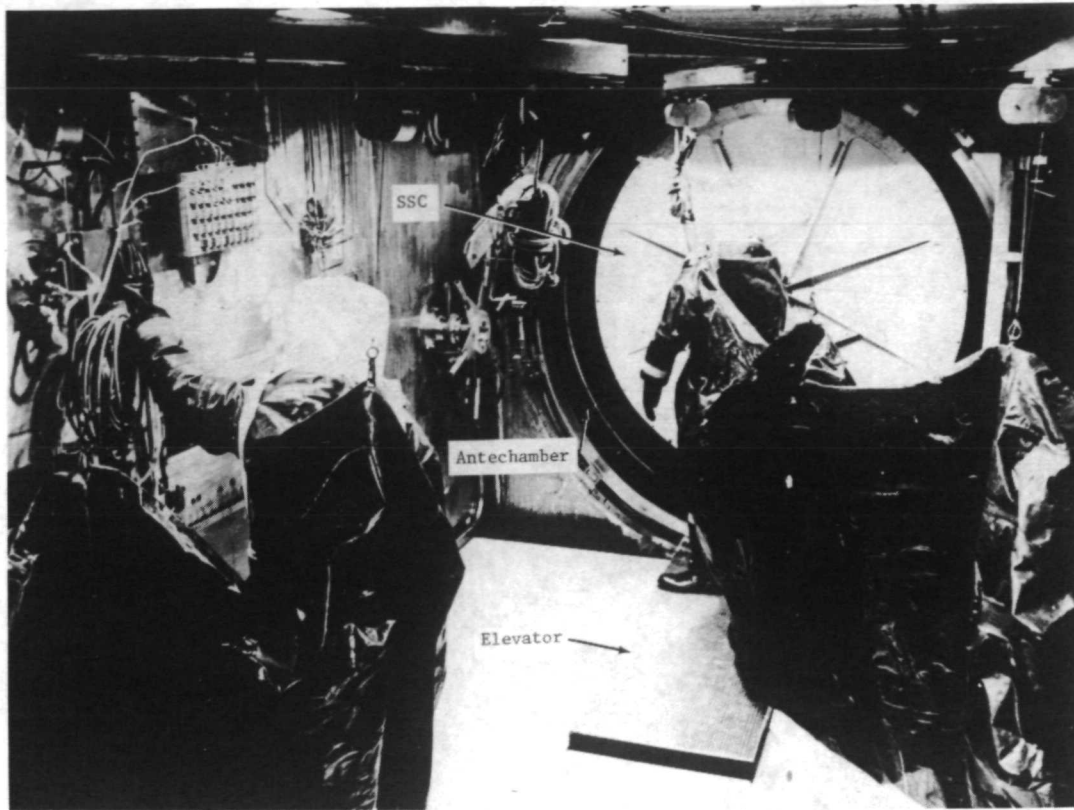
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Figure 12.- Transfer of the SSC into the main chamber.

Autoclave passthrough.- A double-door steam autoclave in the wall of the main chamber is used for the transfer of dry-heat labile materials in and out of the main chamber. It is a modified commercial unit with a specially constructed rack which permits the sterilization and transfer of as much as 0.080 m^3 of biological media per autoclave cycle. The cycle time for a 45-minute sterilization dwell time is approximately 3 hours.

Dry-heat passthrough.- The dry-heat passthrough, with the exception of the steam sterilization capability, is very similar in construction and function to the autoclave pass-through. This passthrough can be manually or automatically controlled and time and temperature can be varied to provide for changing sterilization requirements.

MAST Supporting Subsystems

Gas handling system.- A simplified schematic of the gas handling system is shown in figure 13. This schematic shows the primary gas inputs and metering systems, but omits many pumps and valves and all heat exchangers for the sake of simplicity. This system can deliver unsterile air, nitrogen, and helium at $0.0472 \text{ m}^3/\text{sec}$ and sterile nitrogen and helium at $0.0047 \text{ m}^3/\text{sec}$ to the main chamber, and unsterile air, nitrogen, and helium at $0.012 \text{ m}^3/\text{sec}$ to the antechamber and at $0.0047 \text{ m}^3/\text{sec}$ to the passthroughs.
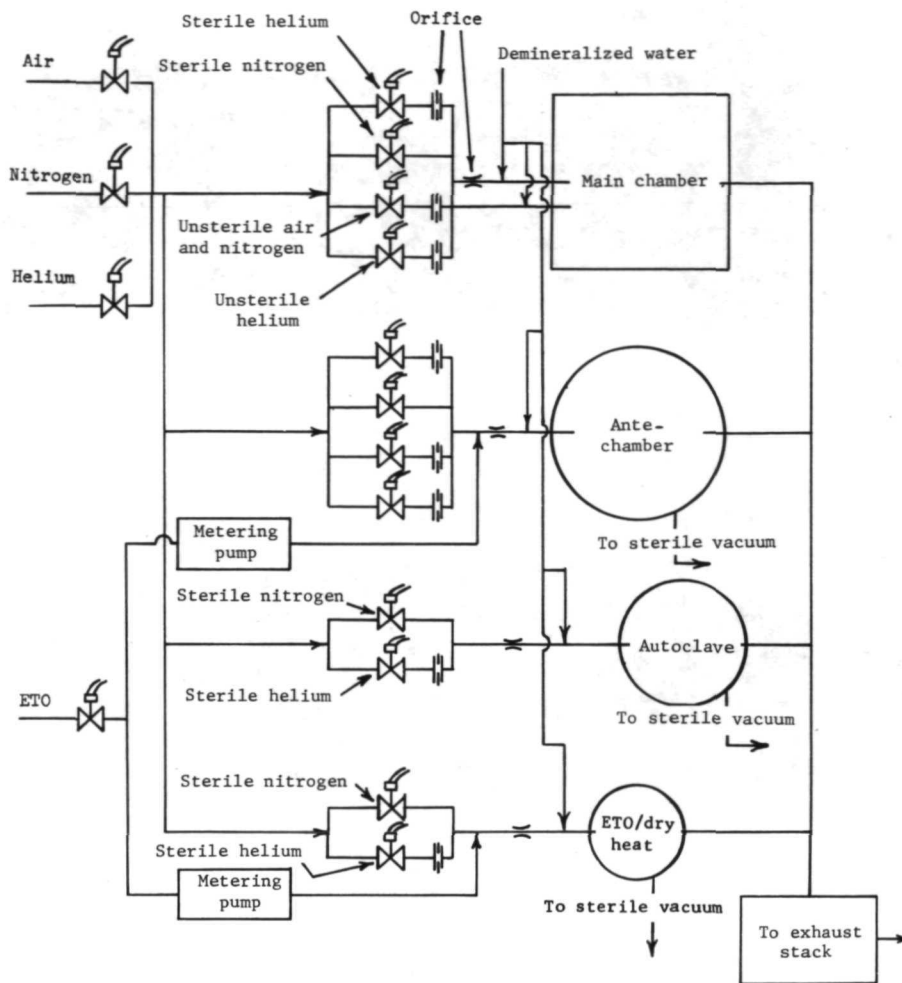
Figure 13.- Gas system schematic.

The control console for each chamber contains electronic logic which selects and actuates the valves, pumps, and heaters as needed to supply conditioned gas to the selected chamber. Figure 14 shows the main-chamber control console display with the controls along the top and sides and the lighted display in the center. The system is equipped with a safety feature which allows anyone planning to work in the main chamber to lock it in the air mode. The TIC units at the top of the console are "temperature indicator controllers," the PIC is a "pressure indicator controller," and the HIC is a "humidity indicator controller." TIC 13 controls the temperature of the hot water in the wall panels; TIC 16 controls the temperature of the gas in the main chamber; and TIC 12 regulates the temperature of the gas entering the main chamber.

PIC 4 controls the gas pressure at the inlet to the circulating blower in the main chamber. This pressure is the lowest pressure in the main chamber and the pressure which was used as the chamber standard for a positive pressure gradient across the

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Figure 14.- Main-chamber control console.

biobarrier. The design of the main-chamber control console is standard for all chambers except where modified to conform to functional variations.

MAST leak-detection system.- Although this system is covered in some detail in the text of this report, the problem generated by the excessive requirements for elastomeric seals requires some additional discussion. The large number of elastomeric seals, primarily silicone rubber, allows more helium to permeate the biobarrier than the leak detector can measure accurately. Therefore, in order to make a quantitative assessment of the total MAST biobarrier leak rates, it is necessary to close off those parts of the system which include elastomeric seals and to sample the remaining networks as a whole. The tests of those parts containing elastomeric seals are conducted on a network-by-network basis and the leak rates from all networks can then be added to give a total leak rate for the whole system.

Heating and cooling systems.- High-temperature water is supplied to the heating panels, tubing, and heat exchangers by 0.2931 MW boiler located in the equipment trailer. This capacity is sufficient to handle the peak demand of heating both the main and antechambers to maximum temperature while holding the dry-heat passthrough at 423 K and the autoclave at 398 K. The hot water is supplied at the outlet of the boiler at

8600 kN/m^2 pressure for forced circulation. A differential pressure regulator across chamber heat exchangers drops the pressure to 7900 kN/m^2 and insures rapid flow through the heat exchangers with minimum temperature drop.

The cold water needed to cool down the system is provided by two cold water reservoirs located under the equipment and operations trailers. These tanks are cooled by a chiller with the capacity for extracting 55.8 kJ.

MAST has separate cold and hot water circulating systems so that chamber heat exchangers can modulate the two relatively fixed temperature inputs to achieve any desired temperature.

Instrumentation and function control.- Temperature and pressure are the two main parameters regulated by the MAST instrumentation and function controls. There are two basic types of operating systems used in temperature control of the MAST. The main chamber and antechamber are semiautomatic systems. The autoclave and dry-heat passthrough are automatic systems which can be overridden manually for process deviations.

The main and antechamber temperature control systems are proportional feedback systems with reset action to eliminate temperature offset. Figure 15 shows a typical control system used in the chambers for gas and wall temperature control. The system uses electronic sensing and signal handling coupled with pneumatic components for valve actuation.

The autoclave and dry-heat passthroughs are modeled after standard commercial units, special features being added to meet stringent spacecraft sterilization requirements. The process instrumentation for temperature control is very similar to that used in the larger chambers and, in addition, may be programed to cycle automatically. This added versatility is necessary in order to minimize personnel requirements during passthrough operations.

Pressure control in all chambers is accomplished by utilizing individual feedback control systems with on-off solenoid-operated valves. The dry-heat passthrough and antechamber have the same functional capabilities, but the dry-heat passthrough is an automatic system with an automatic sequencing device in addition to the sensors, transducers, and controllers used in the antechamber. The autoclave uses standard instrumentation and function controls and is the only chamber capable of being pressurized above 1.5 kN/m^2. This capability is required since autoclaved media must be pressurized to approximately 103 kN/m^2 to prevent boil-off at the sterilization temperature of 394 K.

In addition to the instrumentation required to perform the preceding functions, MAST includes eight 24-channel print recorders for permanent records of thermocouple measurements, a number of 3-channel fold-chart records, and two millivoltmeters con-
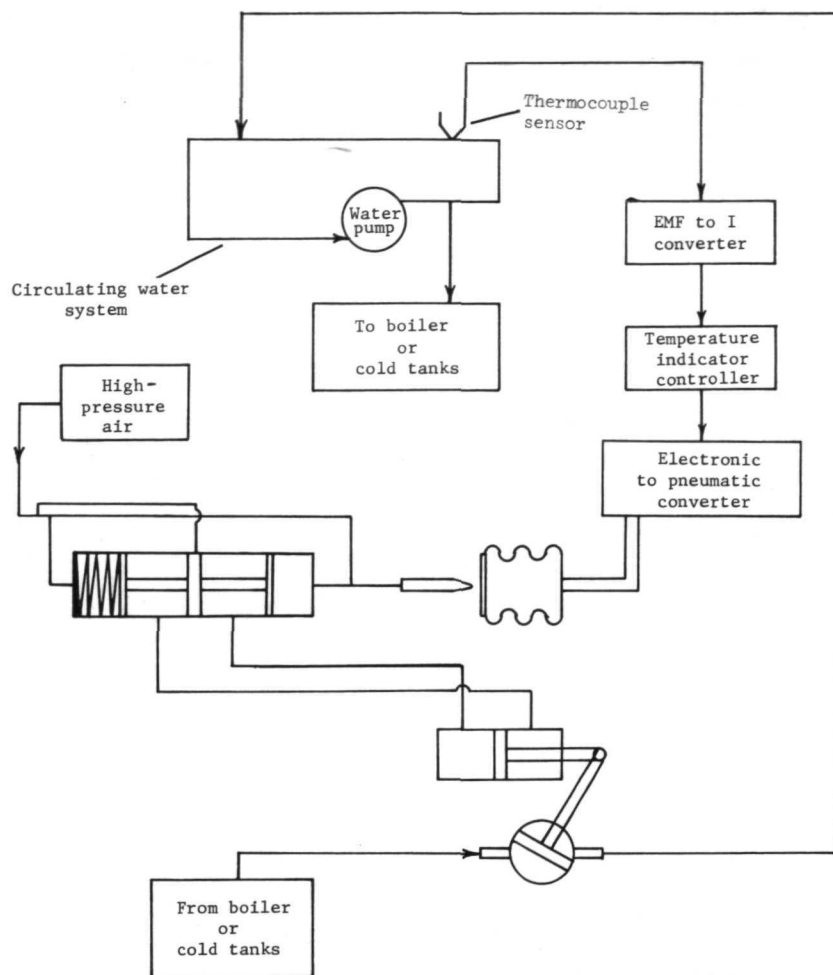
Figure 15.- Temperature control system schematic.

nected to 20 position switches for monitoring coldest point temperatures. Deviation alarms are built into the system to sound an audible as well as visible alarm when temperatures approach critical levels. The system includes many sensors, indicators, switches, and other instruments used in conjunction with ancillary equipment such as the boilers and refrigeration units. All these units are commercial units with no special modifications required for MAST use.

Gas chromatograph system.- This system utilizes a commercial process gas chromatograph to measure helium, oxygen, and nitrogen in samples taken from the MAST chambers.

The measurement range of the analyzer is limited to 0 to 20 percent for helium and to less than 1 percent for oxygen. Nitrogen concentration is measurable from 0 to 100 percent. Gas separation is accomplished by switching of the sample stream from column to

column at the correct time. Control of the sample switching is accomplished by a timer and air-actuated valves.

Each sample line passes through a gas incinerator just after it leaves the chamber. Sampling ports in the main and antechambers are located approximately halfway up the wall of the chamber, whereas the sampling ports in the passthroughs are at the top of the chamber.

APPENDIX B

THE BIOISOLATOR SUIT SYSTEM (BISS)

BISS Tunnel Suits

The BISS tunnels are sealed to the inner walls of the MAST main chamber. They are constructed of heat-resistant material impermeable to micro-organisms. The suit body is a Teflon fabric impregnated with viton and overlayed with a 0.127-mm layer of Teflon film.

The gloves and boots used with the suits were fabricated of an ethylene-propylene polymer, known as EPDM, an extremely flexible and puncture-resistant material. The leg/boot and sleeve/glove fit over a fiber-glass collar and are held in place by adhesives. The joint is sealed and protected by Teflon tubing shrunk around the joint to provide a smooth, nonsnag surface.

The helmets are 1.6-mm type 100 aluminum. Flanges for connecting the helmet to the tunnel suit and for the faceplate attachment are type 6061 aluminum. The faceplate of the helmet is transparent polycarbonate. Silicone rubber foam pads are bonded to the shoulder rest part of the helmet to cushion the operator's shoulders.

Tunnel Suit Support and Rescue Mechanisms

The tunnel suit support and rescue mechanisms include: (1) the tunnel suit suspension system, (2) the suit-donning devices, and (3) the suit emergency reefing equipment. The tunnel suit suspension system is a semicircular track attached to the ceiling of the MAST main chamber, a support beam, and negators (fig. 6). Negators are constant-force spring devices which are connected to the tunnel by means of 1.588-mm-diameter stainless-steel cable. The lifting capacity of the negators is adequate to support the weight of the tunnel. The support beam is hinged near the chamber wall whereas the other end is allowed to swing free through an 180° arc guided by the semicircular track. The suit-donning devices include boot holders, hard tubes, and helmet hooks.

The hard tube (fig. 16) is a 2.75-m-long aluminum cantilevered tunnel over which the BISS tunnel is pulled (reefed) for the purpose of opening the soft tunnel for entering and leaving the BISS suit. The outside surface of the tube is covered with a layer of Teflon to reduce the surface friction.

The helmet hook engages the top of the BISS helmet to hold it while the operator is out of the suit and to make entering the helmet easier. The BISS operator places the hook in the loop on the top of the helmet just prior to leaving the suit (fig. 6).

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Figure 16.- BISS operator enters suit through hard tube.

The suit emergency reefing equipment was provided in case it was necessary, during emergency leaving, to lift an incapacitated BISS operator from the floor to a position in which reefing could be accomplished. It consists of a suit harness, a four-to-one block and tackle with brackets for the attachment of the harness, and a jam cleat (fig. 6). The block and tackle is a 9.5-mm-diameter Dacron line rigged through a pair of heat-resistant phenolic composition blocks. If a BISS operator were to become incapacitated and an emergency exit was necessary, the BISS operator would release the components by simply pulling on the end of the line. He would then extend the block and tackle to the incapacitated operator and hoist the person to a position from which he could be reefed and removed from the suit.

Cooling and Air-Distribution Systems

The cooling and air-distribution systems are an air-cooled undersuit, an air-conditioning unit, and a control console. (See fig. 17.) The air-cooled undersuit is three-layered and has a supply and an exhaust plenum attached to the lower back area. (See fig. 18.) The outer layer of the suit is a black, neoprene-coated, nylon fabric which forms an essentially gas-tight skin. The middle layer is a 6.35-mm-thick polyurethane, open-cell foam which provides an open space between the operator and the outer layer.
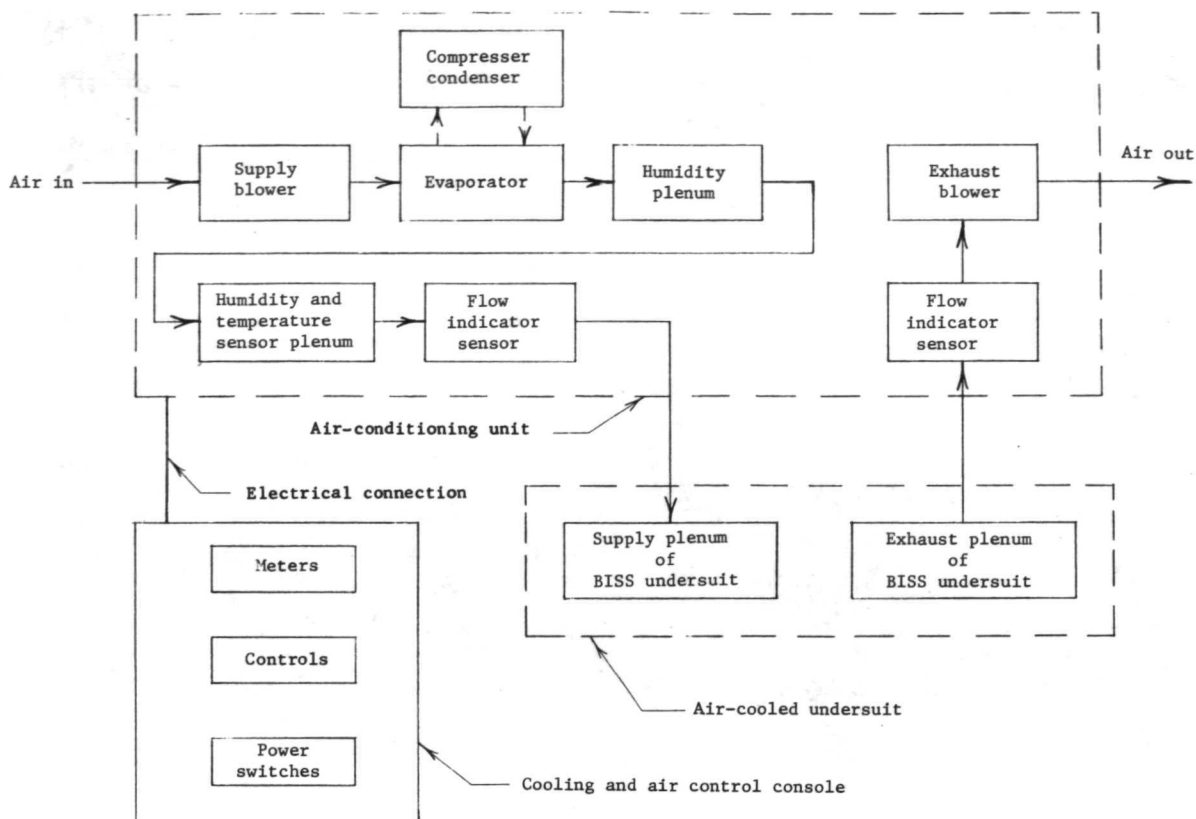
Figure 17.- Block diagram of BISS cooling and air-distribution system.

Cool, dry air circulating through this space cools the operator and removes some of the moisture that the operator generates. The inner layer is a soft, nylon, open-weave chiffon that reduces the coefficient of friction between the undersuit and the cotton under-wear of the operator.

The air-conditioning unit has two high-speed blowers; one for supply and one for exhaust, a compressor-condenser, an evaporator, a humidity plenum, and humidity and temperature instrumentation.

The BISS cooling and air-distribution control consoles (fig. 19) have: (1) variacs to control blower speeds; (2) gages for indicating temperature, relative humidity, and air pressure; (3) power switches for the blowers, the compressor-condenser, and the measuring instrumentation; (4) a warning light and buzzer for low-flow condition in a supply or exhaust line; (5) pilot lights for all power switches; and (6) a pressure regula-tor which controls the air pressure to the atomizing nozzle used to inject water into the air stream to increase humidity.
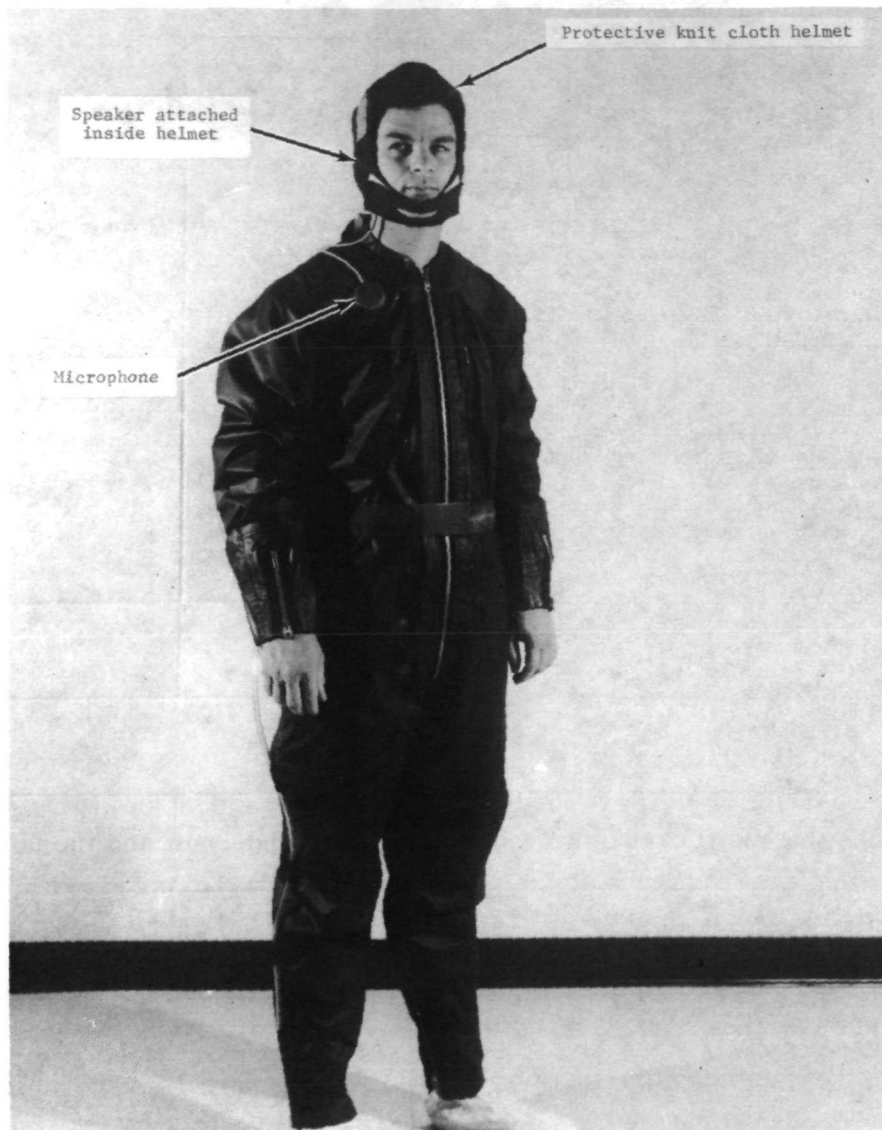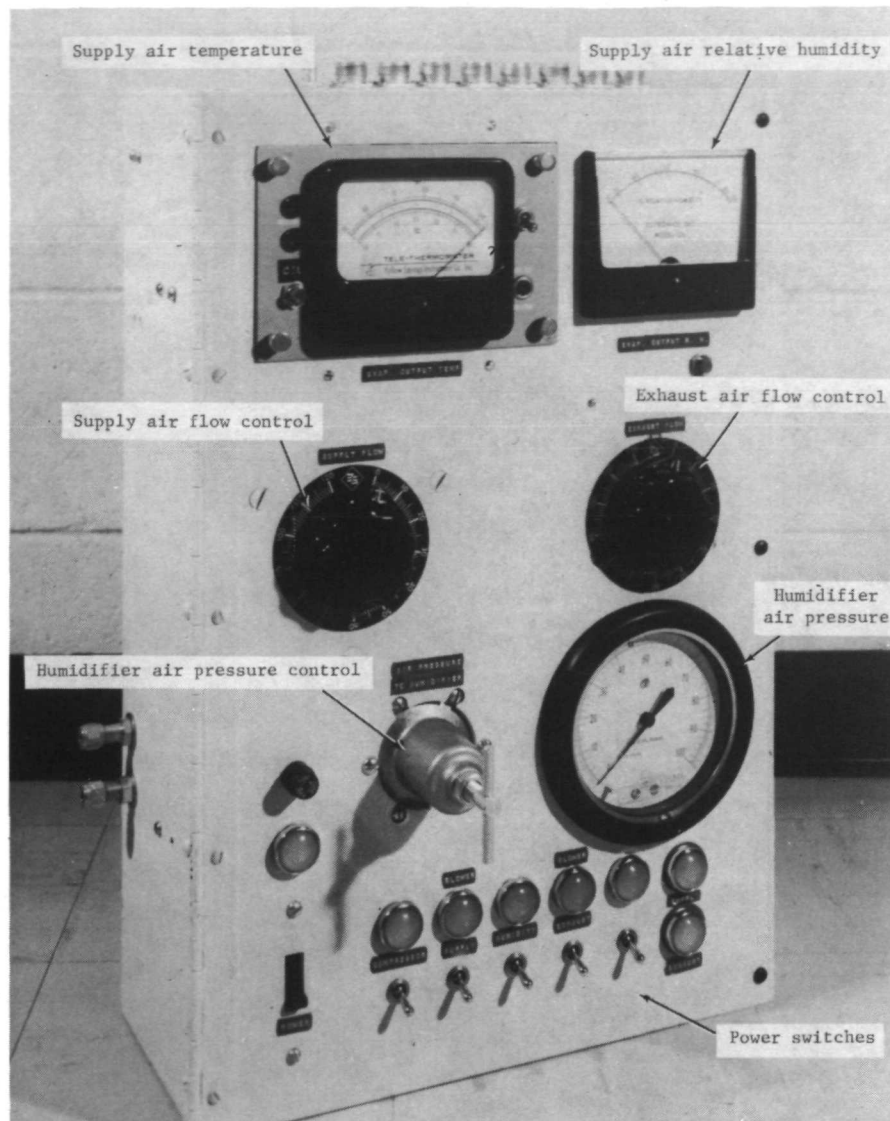
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Figure 18.- Front view of air-cooled undersuit.

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Figure 19.- BISS control console.

Communications

The BISS communications system is essentially a parallel-type system (fig. 20) and each person on line can receive and transmit voice messages to and from everyone else on the circuit. There are five points of communication in the system; the two BISS operators, the main console control, and the two cooling and air control stations. The BISS operators are constantly on line, whereas the other stations must push a button to talk. A separate system with a loudspeaker in the main chamber and a microphone at the main console can be activated to communicate with the BISS operators in case the normal link should fail.
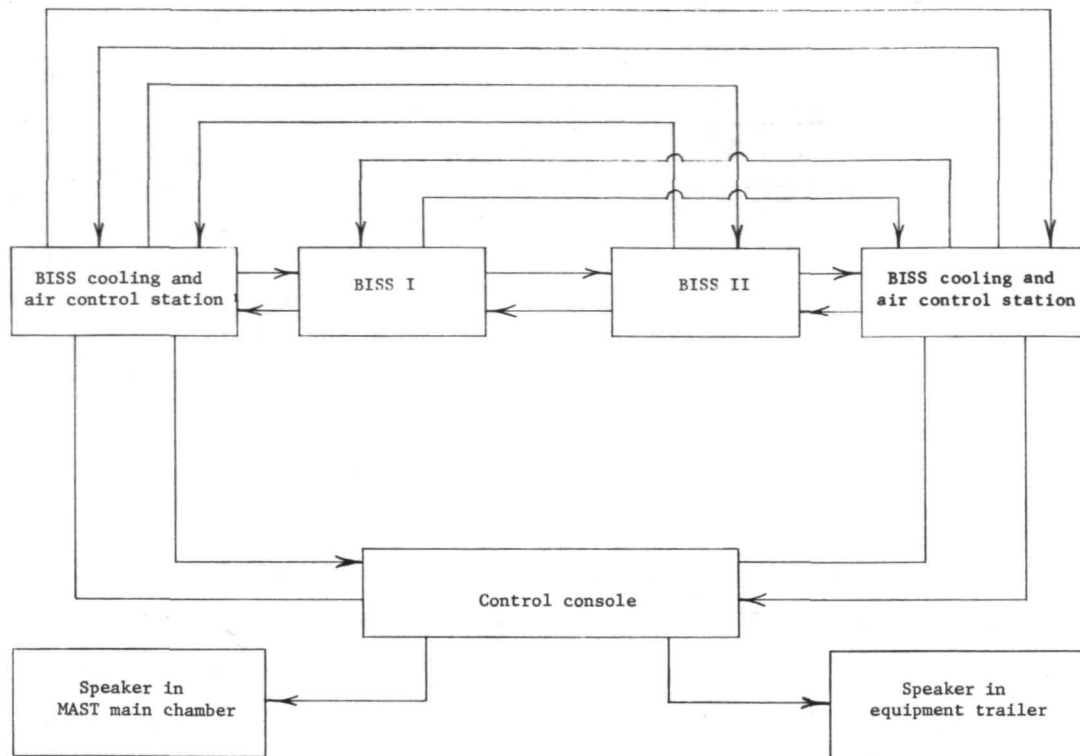
Figure 20.- Block diagram of BISS communications system.

BISS Leak-Detection System

The BISS leak-detection system provides "real-time" monitoring for leaks in the BISS suit and tunnel sections of the MAST biobarrier. This type of leak monitoring is required for early detection of unacceptable leaks. The helium from a leak is mixed with the air flowing from the BISS air-conditioning system and/or from the BISS tunnel door vent (the suit and tunnel should be at a slight negative pressure with respect to ambient) and is carried out with the BISS air-conditioning exhaust air. A small part of the exhaust flow is picked up by a sample retrieval network and carried to a helium mass spectrometer leak detector where a sample is diverted and measured. (See fig. 21.)

The system consists, in addition to some parts of the BISS tunnel suit and air-conditioning systems, of three main elements: (1) the BISS tunnel doors and flanges, (2) a sample retrieval network, and (3) a helium mass spectrometer leak detector.

There are five penetrations in each BISS door; two quick-disconnect passthroughs for the BISS supply and exhaust hoses, one quick-disconnect communications passthrough, one pressure indication and relief diaphragm, and a small vent fitting. The door vent relieves the slight vacuum caused by the BISS supply flow being less than the exhaust flow, and the air flow through the vent serves to flush the BISS tunnel to remove gases from leaks in the tunnel material.
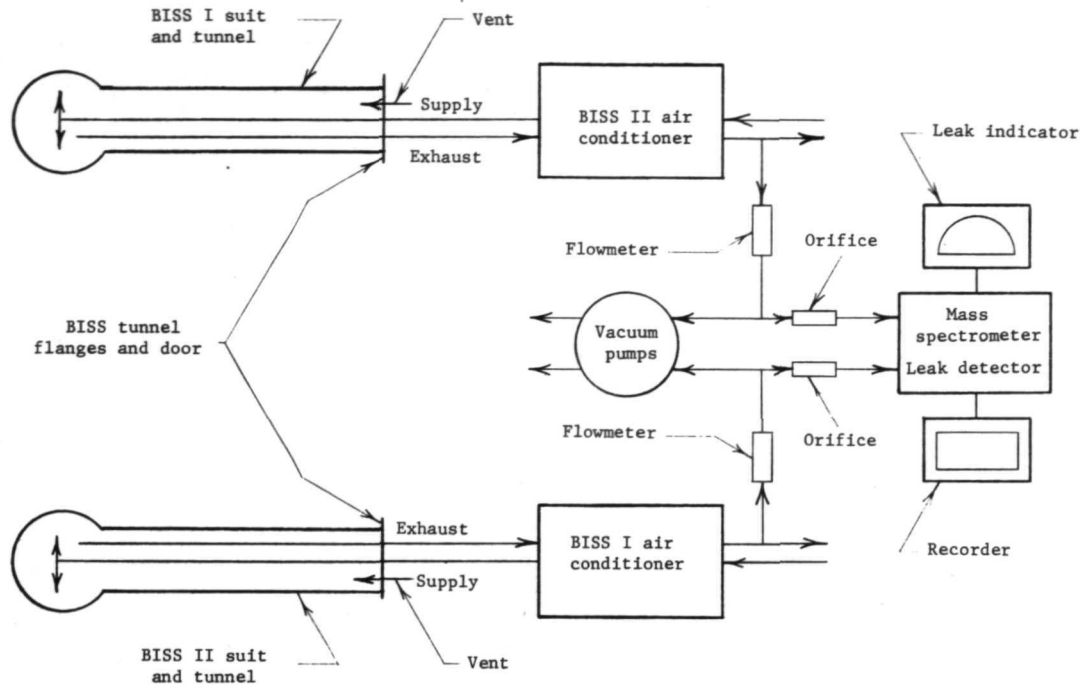
Figure 21.- Flow diagram of BISS leak-detection system.

The sample lines run from the BISS air-conditioning unit exhausts through the flow-meters to the vacuum pumps. Sample flow is about 0.2 m^3/min. Just ahead of the pumps a tee-fitting allows a small sample (0.016 mm^3/sec for BISS I and 0.024 mm^3/sec for BISS II) to be drawn off through the calibrated orifices by the leak-detector pump. These orifices are connected directly to the leak-detector inlet manifold. This arrangement allows a combination of minimal sample transfer times and low sample flow to the leak-detector system.

The BISS leak detector is a double deflection helium mass spectrometer system capable of detecting helium concentrations as low as one part helium in one hundred million parts air or an equivalent air leak of 0.5 μm^3/sec. This high sensitivity was required by the high dilution of the leak by the BISS life-support air and the comparatively low helium concentrations which had to be maintained in the MAST chambers. During the MAST test program, output data from the leak detector were recorded continuously on a single-channel, strip-chart recorder.

APPENDIX C

SUPPORTING TEST EQUIPMENT

Ultrasonic Bioassay Tank System

This system has five major components: (1) the bioassay tank (BAT), (2) four immersible ultrasonic transducers, (3) the ultrasonic generator, power supply, and control console, (4) the recirculating pump and motor, and (5) two high-pressure membrane filter holder units. Components 1, 2, 4, and 5 are shown in figure 7.

The BAT is constructed of 5-mm type 304 stainless steel and is 0.4 m high by 0.9 m wide by 1.1 m long. The BAT has a type 304 stainless-steel cover which is notched to accommodate the rf-shielded cables for the immersible transducers.

The immersible transducers are the electrostrictive type, utilize 1 kilowatt of power, and operate at a basic frequency of 22 kHz. Two transducers are located on one side of the BAT, the other two at one end. Since this type of transducer has a rated efficiency of about 50 percent, this arrangement provides peak watt densities of 3.1 kW/m^2 from the side of the BAT and 4.3 kW/m^2 from the end. A total of 0.304 m^3 of media is required to fill the BAT to the top of the transducers.

The ultrasonic generators supply 1 kilowatt of power each and operate on a 206-volt, single-phase, 60-Hz power source. There are two generators, each of which powers one transducer, and their output can be changed from one set of transducers to the other by means of a switch located on the control console. The control console also contains a power regulation variac which can be used to vary the output of the generator between 0 and 1 kilowatt.

The recirculating pump takes media from the BAT and forces it through the membrane filters and back into the BAT. The pump is powered by an air-cooled 0.746-kilowatt electric motor. It is a semipositive displacement gear type and can pump about 6.3×10^5 mm^3/sec at zero pressure and about 2.5×10^5 mm^3/sec against a back pressure of 620 kN/m^2. The membrane filters used with this system were cellulose ester and had an average pore size of 0.45 micrometer. The BAT, recirculating pump, and filter holders are interconnected by 19-mm-diameter stainless-steel tubing, and the ultrasonic generators and immersible transducers are connected by two Teflon-coated coaxial cables.

Gas Bioassay System (GBS)

This system requires a power input of 500 watts at its maximum sampling rate and utilizes 110-volt 60-cycle power. The media supply and collection reservoirs utilized with this system had a capacity of 4×10^7 mm^3. The GBS is capable of sampling up to

11 m^3/min and utilizes a collection liquid flow of approximately 40 cm^3/min. The recovery efficiency of the system has been experimentally determined to be approximately 12 percent.

Simulated Spacecraft (SSC)

The SSC is anodized 6061-T6 aluminum. The biocanister halves and the aeroshell are 1.9 m in diameter, whereas the landing package is 0.91 m long, 0.65 m wide, and 0.28 m deep. All components used on the landing package panels were flight-qualified components.

APPENDIX D

ENGINEERING RESULTS

The engineering objectives of the MAST program were simply to provide all the physical conditions necessary to prove the feasibility of assembly and repair of sterile spacecraft on a full-scale prototype.

The procedure was to (1) establish a set of process parameters, (2) process a simulated spacecraft (SSC) according to that formula, and (3) verify the efficiency and reliability of MAST in the application of those parameters.

MAST Temperature Control

The first requirement after the basic hardware plan was a closely controlled temperature environment for processing the simulated spacecraft. The objective of maintaining as high a temperature as necessary for sterilization while minimizing thermal degradation of spacecraft parts was achieved through close temperature control. The system was designed to provide a gas temperature of between 293 K and 423 K with a differential not to exceed 273 K to 278 K from the set point.

Temperature rise of the chamber gas and elements (such as the floor) which were heated by the gas was slow because of temperature limitations on the boiler, and a slightly inadequate main-chamber heat exchanger. The floor lagged the gas and wall during heat up and cool down (fig. 22), the main-chamber wall remaining slightly cooler once equilibrium temperature was achieved. During temperature changes in the main floor, the antechamber door hinge plates lagged all other areas.

When the main and antechamber temperatures were set at 398 K during each initial dry-heat sterilization, the recorded temperatures generally remained well within the 278 K band on all gas measurements as well as biobarrier measurements. It was necessary to operate the equipment with the main and antechamber blowers running in order to maintain uniform gas temperatures. Temperature control was also excellent in the antechamber during the high-temperature runs. Gas was circulated in this chamber by two turbulent blowers mounted in the raised floor.

MAST Pressure Control

Because of the possibility of excessive stress on the BISS suit and tunnel, pressure control was found to be more critical than was believed when the MAST was designed. Fortunately, the static-pressure control was better than specified and it was possible to adjust chamber pressure to within 2.5 N/m^2 of any pressure selected, rather than the ±0.124 kN/m^2 specified.
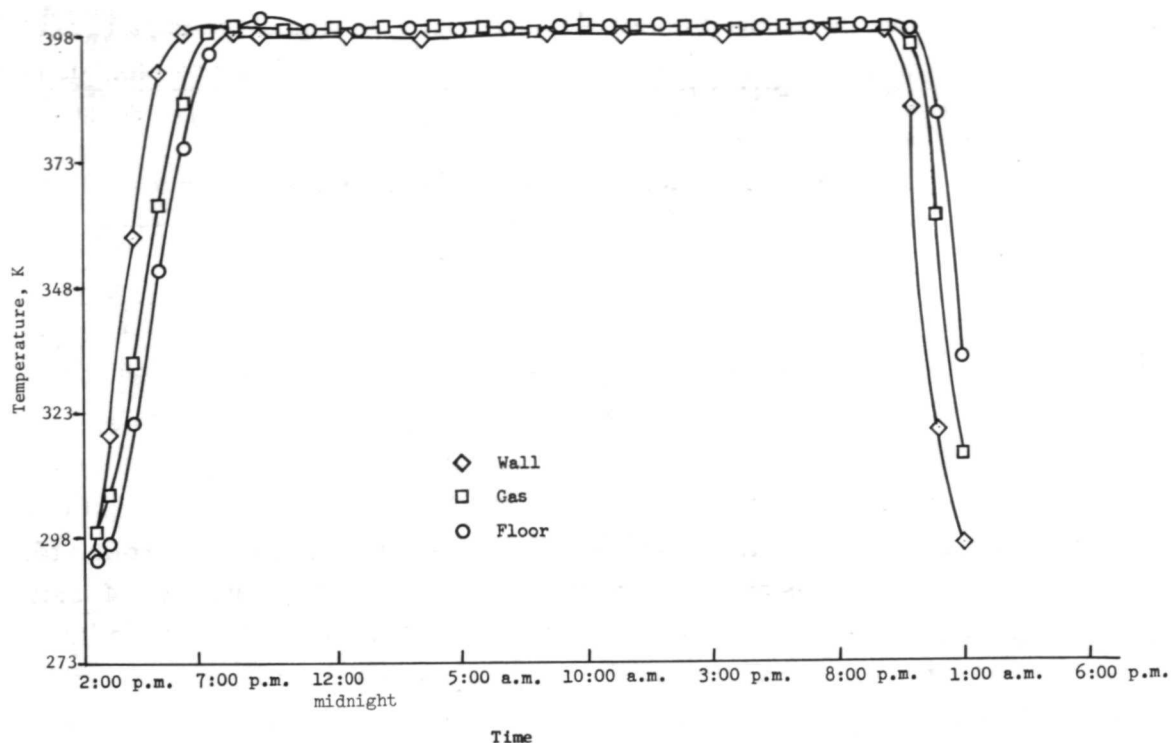
Figure 22.- Main-chamber temperature profile. Cycle 4.

Pressure control during BISS reefing and dereefing required close surveillance. During reefing operations, special care had to be taken to limit the pressure drop because of the BISS tunnel opening up as it went through the main-chamber wall. Rapid reefing coupled with the slow system response could have resulted in a reversal of the pressure gradient necessary to exclude micro-organisms from the chamber. Original plans called for increasing the chamber pressure to 0.249 kN/m^2 or greater during BISS reefing but this increase proved to be impractical because of the excessive strain on the BISS tunnel. A water manometer was used to monitor the chamber pressure closely, particularly during BISS entry and exit.

Ancillary Chambers

Both the dry-heat and autoclave passthroughs operated successfully after some minor modifications. Initially, both of these chambers were unstable during dwell time with sterile nitrogen. The problem was that the minimum volume of gas which could enter a chamber was greater than the volume necessary to arrive at a given pressure level. Thus when a chamber pressure was selected, a "hunting" situation developed, the inlet and outlet solenoids alternately trying to satisfy the system pressure demand. This condition was alleviated by the introduction of a bypass line around the inlet line with a solenoid and adjusting needle valve.

During the tests, steam and nitrogen were injected into the autoclave through the exhaust incinerator. This interim procedure has proven to be acceptable and has demonstrated the technique that could be used for other chambers in the event of incinerator failure.

BISS Suit and Tunnel

The BISS suit and tunnel, in general, provided a satisfactory and workable bio-barrier. Some holes were produced in the bottom of the tunnel during early tests because of contact with sharp edges on the holes in the floor. This problem was eliminated by filing and rounding the sharp edges and by strengthening the tunnel support to keep it off the floor. Some holes developed in the suit due to constant flexing. The areas affected were the elbows, shoulders, and crotch. Most holes were pin-hole size, although a few ranged up to 2.5 mm in diameter. All holes were repaired after each cycle. Although the present BISS suit material was satisfactory for the MAST test program, a material with greater puncture and wear resistance is desirable. The boot and glove material, EPDM, may be useful as a reliable suit material.

Air-Cooled Undersuit

The testing program indicated the need for some minor changes in the undersuit to provide better overall cooling and general comfort. Partial blockage of the exhaust air flow occurred when the BISS operator bent over. This blockage was due to the exhaust inlet being pressed against the back of the operator.

Cooling Supply Lines

A substantial heat loss was encountered in the supply line that carries the cooled air to the undersuit. The air leaving the evaporator was less than 283 K, but the temperature rose to about 294 K to 297 K at the supply outlets of the undersuit. The supply and exhaust lines should be changed to a type using a braided reinforcement. The supply line became 0.46 m to 0.61 m longer because of the constant pressure on it whereas the exhaust line shortened because of the constant vacuum on it.

BISS Communications

Some difficulties with the communications were encountered. The BISS operators had difficulties in hearing because of the air noise from the helmet air-distribution device and to the earplug type speakers, which did not perform satisfactorily. In addition, a lot of noise was fed back from the BISS microphones to the other personnel on the communications network. This condition was due to the high gain needed to pick up the voices of the BISS operators. An Apollo type headset should be used for the BISS operator. These

units employ a small tube extending from the mouth to the microphone on the headband for voice pickup. They are very light and would fit nicely into the protective knit helmet worn by the BISS operator.

An independent amplifier should be used for the BISS suit input and output. The parallel system using one amplifier for inputs and outputs tended to give feedback problems.

The main-chamber speaker partially failed during the second test cycle. It lost volume and was not audible to the BISS operators, because of damage caused by water condensation in the MAST main chamber.

BISS Leak-Detection System

Although the BISS leak-detection system worked reliably throughout the test program, there was a noticeable decrease in the leak-detector sensitivity after the first test cycle. Precalibration negated some of the effects of this problem, but there was a significant decrease in the leak rate shown in subsequent cycles. The loss of sensitivity was apparently due to an increased helium background and leaks in the sample recovery system.

Gas Bioassay System (GBS)

The gas bioassay system (GBS) developed a number of problems during the test program, most of which were due to mechanical changes during initial sterilization. The worst of these changes was a displacement of the disk drive shaft due to deformation of the structure of the sampler during heating and cooling. Repair of the sampler by the BISS operators was possible in most cases and the sampler operated much of the time in spite of the failures. Only during test cycle 3 did down time exceed operational time.

Engineering Conclusions

MAST has proven to be a qualified success in demonstrating the feasibility of assembly and repair of a sterile spacecraft. No technical problem has appeared which has not been minor in nature and has not been or could not be overcome. There are a number of areas in which improvements or adjustments could be made but upgrading is not within the scope of this program. With minor exceptions, all engineering goals were met.

REFERENCES

1. Anon.: Assembly/Sterilizer Facility Feasibility Program. Final Report, Vol. I, Doc. 67SD604 (Contract No. NAS 1-5381), Re-Entry Systems Dep., Gen. Elec. Co., Feb. 21, 1967. (Available as NASA CR-66439.)

2. Farmer, Franklin H.; and Hueschen, Richard M.: Sterile Access Studies in the Pilot Assembly Sterilizer System (PASS). J. Amer. Assoc. Contamination Contr., vol. 2, no. 2, Jan. 1970, pp. 56-62.

3. Anon.: A Research Study To Definitize a Bio-Isolator Suit System (BISS). Doc. 67SD888 (Contract No. NAS 1-6537), Re-Entry Systems Dep., Gen. Elec. Co., Aug. 25, 1967. (Available as NASA CR-66441.)

4. Anon.: A Study of the Possible Movement of Microorganisms Through Small Orifices. AVSSD-0219-68-RR (Contract No. NAS 1-7277), AVCO Corp., 1968. (Available as NASA CR-66703.)

5. Anon.: A Study of Aseptic Maintenance by Pressurization. Contract No. NAS 1-7166, Re-Entry Systems Dep., Gen. Elec. Co., Mar. 1, 1968. (Available as NASA CR-66548.)

6. Cheater, Donald J.; Homsey, Robert J.; Long, Maurice E.; and Sontowski, John F.: A Study of Aseptic Maintenance by Pressurization. Contract No. NAS 1-9174, Re-Entry and Environmental Syst. Div., Gen. Elec. Co., Apr. 1970. (Available as NASA CR-66908.)

7. Cheater, D. J.; Negrey, J. T.; McMenamin, D. L.; and Shull, J. J.: A Study of Aseptic Maintenance by Pressurization. NASA CR-1910, 1971.

8. Anon.: Planetary Quarantine Provisions for Unmanned Planetary Missions. NHB 8020.12, NASA, Apr. 1969.

9. Farmer, F. H.; Tulis, J. J.; Taylor, L. A.; and Pace, V. A., Jr.: Laboratory Evaluation of the Plastic Vacuum Probe Surface Sampler. J. Amer. Assoc. Contamination Contr., vol. 3, no. 2, Sept. 1971, pp. 15-18.

10. Anon.: NASA Standard Procedures for the Microbiological Examination of Space Hardware. NHB 5340.1A, NASA, Oct. 1968.

11. Portner, Dorothy M.; Phillips, Charles R.; and Hoffman, Robert K.: Certification of Probability of Sterilization of Liquid by Filtration. Appl. Microbiology, vol. 15, no. 4, July 1967, pp. 800-807.

12. Puleo, John R.; Favero, Martin S.; and Petersen, Norman J.: Use of Ultrasonic Energy in Assessing Microbial Contamination on Surfaces. Appl. Microbiology, vol. 15, no. 6, Nov. 1967, pp. 1345-1351.

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